Intergovernmental Data Quality Task Force

Uniform Federal Policy for Quality Assurance Project Plans

Evaluating, Assessing, and Documenting Environmental Data Collection and Use Programs

Part 1: UFP-QAPP Manual

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FOREWORD

Part 1 of the Uniform Federal Policy for Quality Assurance Project Plans (the UFP-QAPP Manual) is a consensus document prepared by the Intergovernmental Data Quality Task Force (IDQTF). It provides instructions for preparing Quality Assurance Project Plans (QAPPs) for any environmental data collection operation. The purpose of the UFP-QAPP Manual is to implement the project-specific requirements of ANSI/ASQ E4, *Quality Systems for Environmental Data and Technology Programs - Requirements with guidance for use, Section 6 (Part B)*. The *Uniform Federal Policy for Implementing Environmental Quality Systems* (UFP-QS) was developed by the IDQTF to implement Section 5 (Part A) of ANSI/ASQ E4.

Though the UFP-QAPP Manual is a consensus policy document, it becomes mandatory for new QAPP development for any government department, agency, or program that voluntarily adopts the policy. As is described in the Executive Summary and Introduction, use of the UFP-QAPP Manual will be phased in over time as contracts allow and new QAPPs are required.

Although this UFP-QAPP Manual was initially written for hazardous waste programs and Federal agencies, the IDQTF recognizes that it provides suitable guidance for a wide range of other environmental data collection activities (e.g., permitting, compliance) and anticipates that the policy may be adopted by other programs (e.g., water, air) and by private parties as well as by other Federal agencies, States, and Tribes. Programs and agencies that voluntarily adopt the policy requirements of the UFP-QAPP Manual will be noted on the following Website: http://www.epa.gov/fedfac/documents/intergov_qual_task_force.htm.

Because adoption of the requirements of this UFP-QAPP Manual by Federal departments, agencies, or programs is voluntary, failure to use this guidance is not subject to enforcement action. However, once adopted, the use of this UFP-QAPP Manual and oversight by the adopting Federal department, agency, or program is required to ensure a consistent approach to QAPP development.

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QUESTIONS AND ANSWERS REGARDING THE *UNIFORM FEDERAL POLICY FOR QUALITY ASSURANCE PROJECT PLANS* (UFP-QAPP MANUAL)

I. Background

Q.1 What is a Quality Assurance Project Plan (QAPP)?

A.1 A QAPP is a formal document describing in comprehensive detail the necessary quality assurance (QA), quality control (QC), and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP presents the steps that should be taken to ensure that environmental data collected are of the correct type and quality required for a specific decision or use. It presents an organized and systematic description of the ways in which QA and QC should be applied to the collection and use of environmental data. A QAPP integrates technical and quality control aspects of a project throughout its life cycle, including planning, implementation, assessment, and corrective actions. ANSI/ASQ E4 Section 6 (Part B) requires that a QAPP be approved for all data collection projects. While this UFP-QAPP Manual uses the term QAPP, the information may be incorporated into other planning documents, such as a Sampling and Analysis Plan (SAP), Work Plan, and Field Sampling Plan. This Manual focuses on the required content of any such document, regardless of its name.

Q.2 What is the Intergovernmental Data Quality Task Force (IDQTF)?

A.2 The IDQTF consists of representatives from the U.S. Environmental Protection Agency (EPA), the Department of Defense (DoD), and the Department of Energy (DOE). It was established to address real and perceived inconsistencies and deficiencies in quality control for laboratory data, within and across governmental organizations, that result in greater costs, time delays, and increased risk. The task force is working to ensure that environmental data are of known and documented quality and suitable for their intended uses. It is chaired by the Director of the Federal Facilities Restoration and Reuse Office (FFRRO) and operates as a partnership, reaching decisions through consensus.

Q.3 What is the purpose of the UFP-QAPP Manual?

A.3 The Manual's purpose is to act as a single national consensus guidance document for implementing the requirements of ANSI/ASQ E4, *Quality Systems for Environmental Data and Technology Programs - Requirements with guidance for use*, *Section 6 (Part B)*, consistently and systematically across the Federal agencies involved in the IDQTF (currently EPA, DoD, and DOE). Although ANSI/ASQ E4 Section 6 establishes standards describing the essential elements of a QAPP, it lacks sufficient detail to promote the degree of consistency needed to address the issues of common expectations, conflict, and rework.

Q.4 Will compliance with the UFP-QAPP Manual meet the requirements of QA/R-5, *EPA Requirements for Quality Assurance Project Plans* and QA/G-5, *EPA Guidance for Quality Assurance Project Plans*?

A.4 The UFP-QAPP Manual is consistent with the QAPP requirements outlined in Chapter 5 of the EPA Quality Manual 5360 A1, *EPA Quality Manual for Environmental Programs*. The EPA Quality Staff recognizes that adherence to the Manual will result in compliance with both

QA/R-5 and QA/G-5 for environmental data collection efforts under CERCLA and RCRA at Federal facilities.

Q.5 Why do Federal agencies need another QAPP guidance document?

A.5 Because approaches and requirements for QAPPs differ among Federal agencies, the IDQTF believes it is necessary to implement a QAPP guidance that is applicable to any Federal department, agency, or program. This UFP-QAPP Manual was developed by the IDQTF to provide a common organizational framework and approach to QAPPs. It will reduce conflict by providing all who are involved at Federal facilities with a common set of guidelines and expectations.

II. Basis of the IDQTF UFP-QAPP Manual

Q.6 What is the basis of the UFP-QAPP Manual?

A.6 The basis of the UFP-QAPP Manual is the ANSI/ASQ E4 Section 6 (Part B) requirements. However, because ANSI/ASQ E4 Section 6 lacks sufficient detail, the IDQTF considered other existing QAPP guidance and selected the Region 1 (New England) QAPP guidance as the point of departure for creation of the UFP-QAPP Manual. The Region 1 QAPP guidance has significant breadth of coverage, level of detail, and structured implementation tools, which the IDQTF believes helps to minimize inconsistencies among QAPPs and makes them easier to review (and therefore quicker and cheaper). However, the Region 1 QAPP guidance was significantly modified to make the UFP-QAPP Manual applicable across all Federal agencies, including all EPA Regions.

Q.7 Why wasn't *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5) or *EPA Guidance for Quality Assurance Project Plans* (QA/G-5) used as the base document?

A.7 Although the UFP-QAPP Manual is consistent with both EPA QA/R-5 and QA/G-5, it provides a greater level of detail and more implementation tools than either of those documents. In addition, QA/R-5 applies specifically to EPA-funded projects and often uses EPA-specific language and processes. QA/G-5 is a broad guidance document that lacks the specificity and the implementation tools that the IDQTF believes will make this Federal consensus document so useful.

Q.8 Doesn't the use of the Contract Laboratory Program (CLP) provide sufficient quality assurance for environmental data by ensuring data of known and documented quality?

A.8 No. The CLP provides a series of contract specifications, in the form of a statement of work, that covers laboratory services purchased under specific contracts for Superfund sites. The CLP also provides guidelines for evaluating laboratory conformance to its contract specifications; however, it does not address any of the data usability requirements and therefore does not provide assurance that collected data are appropriate for their intended uses. There are many environmental programs are not covered by CLP, and many aspects of environmental data collection outside its scope (e.g., the systematic planning process, sampling activities, QA oversight). The CLP does not address overall quality systems.

III. Implementation Issues

Q.9 How will the UFP-QAPP Manual be used and implemented?

A.9 The UFP-QAPP Manual is expected to be used to develop QAPPs for managing the collection and use of environmental data at Federal facilities. Each participating Federal department, agency, or program will develop its own implementation plans that recognize the contracts through which the UFP-QAPP Manual will be implemented, the status of previously approved QAPPs, and the stage of the data collection effort.

Since the vast majority of these QAPPs will be generated by contractors, implementation of the UFP-QAPP Manual will be, at least in part, through contracts. Federal Acquisition Regulations (FARs) already require, when appropriate, that contractors maintain high-level quality standards with a quality system based on existing standards, such as E4.

Part 2 of the UFP-QAPP provides three tools to assist in implementation of the UFP-QAPP Manual: Part 2A, the QAPP Workbook; Part 2B, the QA/QC Compendium: Minimum QA/QC Activities; and Part 2C, the Example QAPPs. The QA/QC Compendium outlines minimum QA/QC activities that should be included in a QAPP for all CERCLA projects. These minimum QA/QC activities, although developed for the CERCLA process, are transferable to other environmental data collection and use programs. In addition, the IDQTF is developing a training program to facilitate consistent implementation of the UFP-QAPP Manual.

Q.10 What is the timeframe for implementation?

A.10 Because DoD components and DOE offices each have unique contracting practices, each agency will need to determine its strategy and timeframe for implementation. Implementation could be conducted in phases as existing contracts expire and new ones are instituted.

Q.11 What if I already have an approved QAPP? Will I have to totally rewrite it to comply with the UFP-QAPP Manual?

A.11 No. Previously written and approved QAPPs will not require revision. The UFP-QAPP Manual is aimed at future data collection efforts. Approved project-specific QAPPs will remain acceptable for ongoing data collection activities until the projects are complete.

The UFP-QAPP Manual requires that all QAPPs be reviewed and updated every 5 years, if necessary. This requirement applies to both generic and project-specific QAPPs. If revisions are necessary after the 5-year review, the revised QAPP must comply with the UFP-QAPP Manual. The implementation plan for each participating Federal department, agency, or program should specify exactly how and when QAPPs will be revised.

Q.12 What if I have an approved generic basewide or facilitywide QAPP?

A.12 Generic QAPPs are written to address elements of data collection that generally don't change from site to site or activity to activity. They are always supplemented by project-specific QAPPs, standard operating procedures (SOPs), sampling and analysis plans (SAPs), and field sampling and analysis plans (FSAPs) that address issues that cannot be addressed by the generic QAPP. The UFP-QAPP Manual specifically allows cross-referencing to other documents that contain relevant information. Approved generic QAPPs should not be discarded, but rather

should be referenced in appropriate parts of the project-specific QAPP to help reduce redundancies and create a more focused document.

Q.13 If the UFP-QAPP Manual is the required guidance document for developing QAPPs, what happens if an agency fails to follow it? Will noncompliance result in a Notice of Violation?

A.13 Failure to implement the UFP-QAPP Manual will not subject an agency to a Notice of Violation because implementation of the Manual is voluntarily and would apply only under future intergovernmental MOUs. Because the Manual was not developed or promulgated through the Federal rule-making process, its requirements do not have the force of regulation and are not subject to regulatory enforcement or a Notice of Violation. The purpose of the UFP-QAPP Manual is to assist project teams in creating consistent, high-quality, and easy-to-review documents. Each department, agency, or program must develop its own procedures for assessing nonconformance and initiating appropriate corrective action. **Notice of Violation would be given only in circumstances in which two parties have chosen to make the use of the UFP-QAPP Manual part of an enforceable agreement (such as a Federal Facilities Agreement).** In general, the consequences of not using the UFP-QAPP Manual will be continuation of the conflicts and rework that currently permeate the data collection and review process.

ACRONYMS

AA	Atomic absorption
AFCEE	Air Force Center for Environmental Excellence
ANSI/ASQ	American National Standards Institute/American Society for Quality
ASTM	American Society for Standards and Materials
BOD	Biological oxygen demand
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act of 1980
CLP	Contract Laboratory Program
COC	Contaminants of concern
CRDL	Contract-required detection limit
CWA	Clean Water Act
DoD	Department of Defense
DOE	Department of Energy
DQI	Data quality indicator
DQO	Data quality objective
EPA	Environmental Protection Agency
FS	Feasibility study
FSAP	Field sampling and analysis plan
GC	Gas chromatograph
GC/MS	Gas chromatograph/mass spectrometer
GIS	Geographic information system
GPC	Gel permeation chromatography
GPS	Global positioning system
GW	Groundwater
ICP	Inductively coupled plasma
IDQTF	Intergovernmental Data Quality Task Force
LCS	Laboratory control sample
LFB	Laboratory fortified blank
LIMS	Laboratory information management systems
MARLAP	Multi-Agency Radiological Laboratory Analytical Protocols (Manual)
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MCL	Maximum contaminant level
MDL	Method detection limit
MOU	Memorandum of understanding
MPC	Measurement performance criteria
MQO	Measurement quality objectives
MS/MSD	Matrix spike/matrix spike duplicate
MSR	Management systems review
NEIC	National Enforcement Investigations Center
NIST	National Institute of Standards and Technology
NPDES	National Pollutant Discharge Elimination System
NPL	National Priorities List
PA/SI	Preliminary assessment/site investigation
PARCC	Precision, accuracy, representativeness, completeness, and comparability
PCBs	Polychlorinated biphenyls
PDF	Portable document format

ACRONYMS (continued)

PT	Proficiency testing (previously known as performance evaluation (PE) sample)
PQOs	Project quality objectives
PRP	Potentially responsible party
QA	Quality assurance
QC	Quality control
QS	Quality system
QAPP	Quality Assurance Project Plan
QL	Quantitation limit
QMP	Quality management plan
RCRA	Resource Conservation and Recovery Act
RI	Remedial investigation
RIC	Reconstructed ion chromatogram
RPD	Relative percent difference
RSD	Relative standard deviation
RT	Retention time
SAP	Sampling and analysis plan
SD	Standard deviation
SDG	Sample delivery group
SDWA	Safe Drinking Water Act
SOP	Standard operating procedure
SQLs	Sample quantitation limits
SRM	Standard reference material
SVOC	Semivolatile organic compound
SW	Surface water
TCLP	Toxicity characteristic leaching procedure
TSA	Technical systems audit
UFP	Uniform Federal Policy
USACE	United States Army Corps of Engineers
VOA	Volatile organic analytes
VSP	Visual Sample Plan

EXECUTIVE SUMMARY

Introduction

Part 1 of the *Uniform Federal Policy for Quality Assurance Project Plans* (the UFP-QAPP Manual), prepared by the Intergovernmental Data Quality Task Force (IDQTF), provides instructions for preparing Quality Assurance Project Plans (QAPPs).[1] It is the companion document to the IDQTF's *Uniform Federal Policy for Implementing Environmental Quality Systems* (UFP-QS). The UFP-QS was developed to consistently implement the quality system requirements of *ANSI/ASQ E4, Quality Systems for Environmental Data and Technology Programs - Requirements with guidance for use, Section 5 (Part A)*. Similarly, this UFP-QAPP Manual has been developed to consistently implement the project-specific requirements in Section 6 of that standard (ANSI/ASQ E4). This Manual requires that a QAPP be approved for all environmental data collection projects. The QAPP will integrate technical and quality control aspects of a project throughout its life cycle, including planning, implementation, assessment, and corrective actions. The QAPP will present the steps that will be taken to ensure that environmental data collected are of the correct type and quality required for a specific decision or use. It will present an organized and systematic description of the ways in which quality assurance (QA) and quality control (QC) will be applied to the collection and use of environmental data.

The UFP-QAPP Manual was developed as a joint initiative between the U.S. Environmental Protection Agency (EPA), the Department of Defense (DoD), and the Department of Energy (DOE). The purpose of the Manual is to provide a single national consensus document for consistently and systematically implementing the project-specific requirements of ANSI/ASQ E4 across the Federal agencies involved in the IDQTF (currently EPA, DoD, and DOE). It is consistent with EPA's existing QAPP guidance (QA/G-5) and QAPP requirements (QA/R-5). In addition, implementation of the UFP-QAPP Manual will help to ensure the quality, objectivity, utility, and integrity of environmental information that the Federal government disseminates as required by the Information Quality Guidelines (EPA/260R-02-008, October 2002).

Part 2 of the UFP-QAPP provides three tools to assist in implementing this UFP-QAPP Manual. Part 2A is the QAPP Workbook Part 2B, the QA/QC Compendium: Minimum QA/QC Activities, outlines QA/QC activities that should be included in a QAPP for all CERCLA projects. These activities, although developed for the CERCLA process, are transferrable to other environmental data collection and use programs. Part 2C presents Example QAPPs.

Background

Many Federal agencies have independently created their own QAPP guidance. EPA has one QAPP requirements document and one guidance document that encompass all the systematic planning process elements that should be addressed in a QAPP. These documents are QA/R-5, *EPA Requirements for Quality Assurance Project Plans* (requirements), and QA/G-5, *EPA Guidance for Quality Assurance Project Plans* (guidance). The EPA Quality Staff recognizes that adherence to the UFP-QAPP Manual will result in full compliance with both QA/R-5 and QA/G-5 for environmental data collection efforts under CERCLA and RCRA at Federal facilities.

[1]This UFP-QAPP Manual is based on guidance developed by EPA Region 1. It has been modified by a workgroup of the IDQTF to reflect EPA, DoD, and DOE comments on the Region 1 guidance, to remove Region 1-specific elements, and to address data review approaches identified by members of the IDQTF.

Because approaches to and requirements for QAPPs differ among Federal agencies, the IDQTF believes it is necessary to implement consistent QAPP requirements that are applicable to any Federal department, agency, or program that adopts the UFP-QAPP Manual. Manual provides an organizational framework and approach to QAPP preparation with a common set of expectations and guidelines.

Although the States were not involved in the development of this Manual, the IDQTF recognizes the importance of their role in the review and approval of QAPPs. States are encouraged to review and approve QAPPs based on the requirements in this Manual.

Scope

This Manual provides Federal departments, agencies, and programs with policy and guidelines for developing QAPPs for management of environmental data collection and use. This document represents a voluntary consensus policy. Implementation is therefore not subject to oversight by another Federal department, agency, or program, or to a Notice of Violation if one department, agency, or program fails to implement all or part of the policy. However, once the requirements of this Manual are adopted by a Federal department, agency, or program, its use is mandatory within that department, agency, or program.

Each participating Federal department, agency, or program will develop its own implementation plan. It is anticipated that the use of the Manual will be phased in and that it will be used to develop the initial and revised versions of QAPPs for managing the collection and use of environmental data at Federal facilities. It is not intended to apply retroactively to previously approved QAPPs.

Overview of This Manual

The UFP-QAPP Manual covers a variety of topics regarding QAPP preparation, some of which are often included in other documents (e.g., sampling and analysis plans, work plans), and encompasses EPA's Systematic Planning Process. Several principles are important for understanding the Manual:

- Although designed for use in support of hazardous waste programs (CERCLA and RCRA) at Federal facilities, the UFP-QAPP Manual is applicable to any environmental program for which field data will be collected and analyzed.

- Part 2B of the UFP-QAPP outlines minimum QA/QC activities that should be included in all CERCLA project QAPPs. These minimum QA/QC activities, although developed for the CERCLA process, are transferrable to other environmental data collection and use programs.

- The content and level of detail required for individual QAPPs will vary according to the work being performed. Project planners are encouraged to use a "graded approach" when preparing QAPPs. In other words, the degree of documentation, level of effort, and level of detail will vary based on the complexity of the project.

- The UFP-QAPP Manual recommends, but does not require, the use of tables and charts (called worksheets) to document the requirements of the QAPP. The specific elements of the various tables and charts are outlined in the Manual, and templates are provided in the QAPP Workbook (Part 2A of the UFP-QAPP). The use of the worksheets is expected to expedite the review of QAPPs by an approval authority.

- The UFP-QAPP Manual is designed to be used to generate both generic and or project-specific QAPPs. When elements required by the Manual are present in other documents (e.g., SOPs), careful cross-referencing of these other documents can be used in lieu of repeating information.

- Depending on the implementation plan of each Federal department, agency, or program, existing QAPPs should not have to be rewritten when the requirements of the UFP-QAPP Manual are adopted. The Manual's requirements will be applicable to QAPP revisions and to new QAPPs.

Related IDQTF Documents and Products

Part 2 of the UFP-QAPP provides supplementary materials for use with the UFP-QAPP Manual:

- Part 2A, "QAPP Workbook," contains blank worksheets that will assist with the preparation of QAPPs by addressing specific requirements of the Manual.

- Part 2B, "Quality Assurance/Quality Control (QA/QC) Compendium: Minimum QA/QC Activities," specifies minimum QA/QC activities for environmental data collection and use for hazardous waste projects.

- Part 2C, "Example QAPPs," provides several example QAPPs that are based on the requirements in the Manual. They use the worksheets recommended in this Manual to demonstrate how they may be completed to write a QAPP.

Organization of This Manual

This document is organized into five major sections. The introductory section describes the nature of this policy and provides detail on the overall approach. Each of the subsequent four sections addresses one of the four major QAPP element groups: Project Management and Objectives, Measurement/Data Acquisition, Assessment and Oversight, and Data Review. In addition, Appendix A provides additional details for the content of SOPs.

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1.0 INTRODUCTION

The complexity of environmental data collection operations demands that a systematic planning process and structure for quality be established if decision-makers are to have the necessary confidence in the quality of data that support their decisions. This process and structure must include the means to determine whether the data are fully usable and what to do if they are not. This process and structure are provided by the quality system used by the organization conducting the environmental data operations.

The lead organization (see Section 1.3.1) must develop, operate, and document quality systems to ensure that environmental data collected or compiled for environmental programs are scientifically sound, of known and documented quality, and suitable for their intended use.

In order to assist lead organizations with the implementation of their quality systems, the *Uniform Federal Policy for Implementing Environmental Quality Systems* (UFP-QS) was developed to facilitate consistent implementation of the quality system requirements of Section 5 (Part A) of ANSI/ASQ E4, *Quality Systems for Environmental Data and Technology Programs - Requirements with guidance for use* (January 1995 superceded by February 2004). Similarly, the *Uniform Federal Policy for Quality Assurance Project Plans* (UFP-QAPP) has been developed to facilitate consistent implementation of the project-specific requirements of Section 6 (Part B) of E4, as well as *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5, EPA/240/B-01/003, March 2001) and *EPA Guidance for Quality Assurance Project Plans* (EPA QA/G-5, EPA/600/R-98/018, February 1998). This Manual is Part 1 of the UFP-QAPP. It provides instructions for the preparation of quality assurance project plans (QAPPs). Part 2 provides implementation tools for Part 1.

This introduction outlines the purpose and organization of the UFP-QAPP as well as the purpose and content of a QAPP; the QAPP review, approval, and modification processes; and the roles and responsibilities of those involved in QAPP development.

1.1 Uniform Federal Policy for Quality Assurance Project Plans

1.1.1 Scope

This document provides policy and guidelines to Federal departments, agencies, and programs for developing QAPPs for the management of environmental data collection and use. This document represents a voluntary consensus policy; therefore, implementation is not subject to oversight by another Federal department, agency, or program or to a Notice of Violation for failure to implement all or part of the policy. **However, once a Federal department, agency, or program, adopts the requirements of this document, its use is mandatory within that department, agency, or program.**

Each participating Federal department, agency, or program will develop its own implementation plan. It is anticipated that use of the Manual will be phased in as it is used to develop the initial and revised versions of QAPPs for managing the collection and use of environmental data at Federal facilities. It is not intended to apply retroactively to previously approved QAPPs.

1.1.2 Purpose

This UFP-QAPP Manual is intended to provide instructions for QAPP preparation in accordance with Section 6 (Part B) of ANSI/ASQ E4. Once adopted, the requirements presented in this UFP-QAPP Manual must be adhered to by the lead organization and its contractors when developing new QAPPs that guide the performance of environmental data collection operations. The requirements of the UFP-QAPP Manual must also be adhered to by regulatory entities collecting environmental data for oversight purposes. In addition, review and approval of QAPPs by EPA must be in accordance with the requirements of this UFP-QAPP Manual.

This UFP-QAPP Manual is not program-specific and is intended to be as comprehensive as possible. Since the content and level of detail in QAPPs vary according to the work being performed and the intended use of the data, parts of this UFP-QAPP Manual may not be applicable to all programs. However, each of the sections and subsections in the Manual must be addressed in the QAPP to the degree appropriate for the data collection activity, even if only by the statement "not applicable." To the extent practicable, information should be provided in tabular format. However, sufficient written discussion should accompany the tables to facilitate understanding.

To assist in compiling critical QAPP information, Part 2 of this UFP-QAPP provides three supplemental documents:

- Part 2A, "QAPP Workbook," provides blank worksheets.
- Part 2B, "Quality Assurance/Quality Control Compendium: Minimum QA/QC Activities," outlines QA/QC activities that should be included in a QAPP for all CERCLA projects.
- Part 2C, "Example QAPPs," provides examples of completed worksheets and shows how to fulfill the requirements of this UFP-QAPP Manual.

The QAPP worksheets can be taken to project scoping sessions and completed during the project planning stage. Subsequently, the worksheet information can be presented in tabular format in the QAPP. The worksheets are designed to ensure consistent content and presentation of information in a project-specific QAPP. Use of a consistent format for QAPPs is expected to streamline the review of QAPPs by regulators and others. If the QAPP worksheets are not used, information required by the worksheets must still be presented in the QAPP, as appropriate to the project.

1.1.3 Organization

The remainder of this UFP-QAPP Manual is organized in accordance with the four elements of a QAPP (see Section 1.2.3):

- Project Management and Objectives
- Measurement and Data Acquisition
- Assessment and Oversight
- Data Review

Appendix A to this Manual provides additional guidance for Standard Operating Procedures.

1.2 Quality Assurance Project Plans

The QAPP integrates all technical and quality aspects for the life cycle of the project, including planning, implementation, and assessment. The ultimate success of an environmental program or project depends on the quality of the environmental data collected and used in decision-making, and this quality depends significantly on the adequacy of the QAPP and on its effective implementation. The QAPP documents how quality assurance and quality control are applied to an environmental data collection operation to ensure that the results obtained will satisfy the stated performance criteria. It is important to note that quality assurance and quality control are defined and used differently. Quality assurance refers to the system of management activities, whereas quality control refers to the system of technical activities that measure performance against defined standards.

All QAPPs must, at a minimum, address all elements detailed in this UFP-QAPP Manual. In some cases, certain elements will not be appropriate for a particular project. Requirements of the Manual that do not apply can be addressed with a simple statement of why the information is not relevant or with a cross-reference to another approved document in which the information appears.

> The QAPP document may be referred to by another name or incorporated into other project planning documents. The document for some programs or projects may be referred to as a Sampling and Analysis Plan (SAP), Work Plan, Field Sampling Plan, etc. This UFP-QAPP Manual focuses on the required content of any such document.

A QAPP is often subject to regulatory review and approval by EPA or the other appropriate approval authority (including, but not limited to, EPA-delegated approval authorities) prior to sample collection.

Figure 1 presents the life cycle of a QAPP.

Environmental Problem

↓

Assemble Project Team

↓

Schedule and Conduct Scoping Sessions

↓

Plan Project and Compile Information Required by QAPP Worksheet Information

↓

Prepare Project-Specific or Generic QAPP

↓

Perform Internal Review

↓

Submit QAPP for External Approval

↓

Revise QAPP as Required and Submit for External Approval

↓

*** QAPP APPROVED ***

↓

Implement QAPP as Prescribed

↓

Amend QAPP as Needed To Address Unexpected Conditions

↓

Submit Amendments for Approval or Obtain and Document Verbal or Electronic Approval

↓

Modify Project Work After Approval Received

↓

Archive QAPP in Project or Program File

↓

Review QAPP Annually. Revise QAPP if Necessary, When Directed by the Approval Authority or, at a Minimum, Every 5 Years

Figure 1. Life Cycle of a QAPP

1.2.1 Purpose

The purpose of a QAPP is to document the planned activities for environmental data collection operations and to provide a project-specific "blueprint" for obtaining the type and quality of environmental data needed for a specific decision or use. The planning should include the "stakeholders" (e.g., data users, data producers, decision-makers) to ensure that all needs are defined adequately and that the planning for quality addresses those needs. While time spent on such planning may initially seem unproductive and costly, the penalty for ineffective planning often is greater conflict and extensive reworking, which results in increased cost and lost time.

The QAPP serves several purposes:

- As a *technical planning document*, it identifies the purpose of the project, defines the project quality objectives, and outlines the sampling, analytical, and quality assurance/quality control (QA/QC) activities that will be used to support environmental decisions.
- As an *organizational document*, it identifies key project personnel, thereby facilitating communication.
- As an *assessment and oversight document*, it provides the criteria for assessment of project implementation and for QA and contractor oversight.

QAPPs and Quality Management Plans

The *Uniform Federal Policy for Implementing Environmental Quality Systems* requires documentation of an organization's quality system in a quality management plan (QMP). A QMP is a formal document that describes the quality system in terms of the organization's structure, the functional responsibilities of management and staff, the lines of authority, and the required interfaces for those planning, implementing, and assessing all activities conducted. Organizations participating in the project (e.g., Federal agency, prime contractor, laboratory) must have a QMP or some other documentation of a quality system. The management, organization, and personnel responsibilities outlined in the QAPP should be consistent with that quality system.

1.2.2 Types of Quality Assurance Project Plans

QAPPs can be of two types:

- A *generic QAPP* is an overarching plan that describes the quality objectives and documents the comprehensive set of standard operating procedures (SOPs) for sampling, analysis, QA/QC, and data review that are specific to a **site** (e.g., facility, base) or to an **activity** (e.g., compliance with an environmental program such as Safe Drinking Water Act, repetitive groundwater monitoring). A generic QAPP may be applicable to a single site with multiple activities (e.g., soil, groundwater, and surface water sampling) or to a single activity that will be implemented at multiple sites (e.g., same type of air monitoring at several Air Force bases) or at multiple times

(e.g., a groundwater monitoring program that will sample the same locations every 3 months for 5 years).

A generic program QAPP may serve as an umbrella under which project-specific tasks are conducted over an extended period of time. Project or task-specific information not covered by the umbrella is documented in detailed sampling and analysis plans (SAPs) or work plans, which use the generic QAPP as an informational reference whenever appropriate. The use of generic QAPPs, with supplemental project-specific QAPPs as needed, is a significant opportunity to use a graded approach, reducing repetition and streamlining the QAPP development, review, and approval process (see Section 1.2.4).

When a generic QAPP is being developed that will apply across multiple EPA Regions or regulatory approval authorities, the scoping process must involve those entities early in the development of the QAPP. Receiving input early will help streamline review and approval of the generic QAPP.

- A *project-specific QAPP* provides a QA blueprint specific to one project or task. Project-specific QAPPs are used for projects of limited scope and time and, in general, can be considered the SAP or work plan for the project. A project-specific QAPP for each site or activity may be needed to supplement a generic QAPP.

1.2.3 Required QAPP Element Groups and the Systematic Planning Process

There are four basic element groups addressed in a QAPP: Project Management and Objectives (Section 2), Measurement/Data Acquisition (Section 3), Assessment/Oversight (Section 4), and Data Review (Section 5). As shown in Figure 2, the four QAPP element groups represent the pieces of a project's life cycle, which are integrated through the use of scoping sessions.

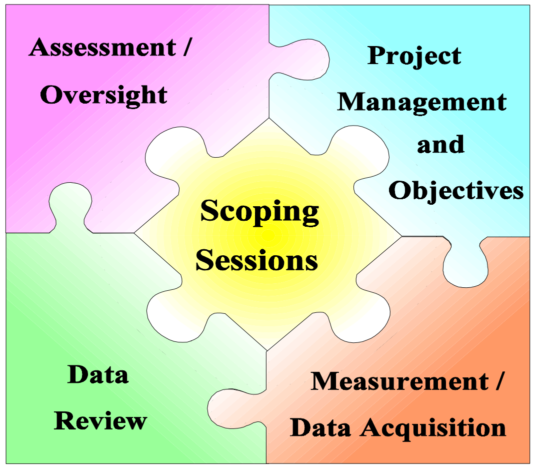

Figure 2. QAPP Process Elements

The four basic element groups of a QAPP present a framework consistent with *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5), which requires use of a systematic planning process. The inconsistencies in language between the UFP-QS and the UFP-QAPP Manual are due to the different purposes of the documents. The UFP-QS, which outlines a six-step process, serves as a high-level policy document for implementing quality systems, as defined in ANSI/ASQ E4. Thus, it describes the systematic planning process at a conceptual level. This UFP-QAPP Manual is an implementation guide that significantly expands on the UFP-QS. Table 1 identifies how the four QAPP element groups outlined in the UFP-QAPP Manual and the detailed systematic planning process shown in Figure 13 (Section 2.6.1) address the six planning process elements outlined in the UFP-QS Section 7.2.

Table 1. Comparison of UFP-QS and UFP-QAPP Systematic Planning Process

Systematic Planning Process Elements (UFP-QS)	QAPP Element Group	Systematic Planning Process Steps (UFP-QAPP)
Establishment of a Team-Based Approach to Planning	Project Management and Objectives	ID Lead Organization, Approval Authority, and Project Team; ID Project Organization and Responsibilities; Schedule and Convene Scoping Sessions *(Sections 2.3, 2.4)*
Description of the Project Goal, Objectives, and Questions and Issues To Be Addressed	Project Management and Objectives	Define Environmental Problem *(Sections 2.5, 2.6, 2.7)*

Table 1. Comparison of UFP-QS and UFP-QAPP Systematic Planning Process (continued)

Systematic Planning Process Elements (UFP-QS)	QAPP Element Group	Systematic Planning Process Steps (UFP-QAPP)
Identification of Project Schedule, Resources (Including Budget) Milestones, and Any Applicable Requirements	Project Management and Objectives	Develop Project Schedule *(Section 2.8)*
Matching of the Data Collection and Analysis Process to Project Objectives	Measurement/ Data Acquisition	Determine the "Type" of Data Needed; Determine the "Quality" of Data Needed; Determine the "Quantity" of Data Needed; Develop Sampling Design Rationale *(Sections 3.1.1, 3.4)*
Identification of Collection and Analysis Requirements	Measurement/ Data Acquisition	Determine Sampling Requirements; Select Sampling SOPs that have Documented QC Limits Supporting the MPC (Obtain Services of On-Site Sampling Group); Develop Analytical Requirements; Select On-site/Off-site Analytical Methods/SOPs that have Documented QC Limits Supporting the MPC *(Sections 3.1.2, 3.2, 3.3, 3.5, Appendix A)*
Description of the Generation, Evaluation, and Assessment of Collected Data	Assessment/ Oversight Data Review	Determine Quality Assurance Assessments that will be Performed and Identify Organizations Performing Assessments; Decide How Project Data will be Evaluated After Review to Determine if the User's Needs Have Been Met *(Sections 4.0, 5.0)*

1.2.4 QAPP Requirements

The information specified in Table 2 must be provided in all QAPPs submitted to EPA or the delegated regulatory authority. Table 2 also provides a crosswalk between the QAPP element groups, the required QAPP sections, and the QAPP worksheets, which are in the QAPP Workbook that accompanies this Manual (Part 2A). It is important to remember that worksheet use is optional, although desirable, and that required information will be project-specific. As the following text box states, other project documents may be cross-referenced and, as appropriate, provided for approval.

Note: All QAPP worksheets, when used, should be completed with project-specific information. If the QAPP worksheets are not used, relevant information required on the worksheets must still be presented in the QAPP. In addition, QAPP preparers are encouraged to develop additional tables, as appropriate to the project. Sufficient written discussion in text format should accompany all tables. Certain sections, by their nature, will require more written discussion than others. In particular, Section 3.1.1 should provide an in-depth explanation of the sampling design rationale, and Section 5.2 should describe the procedures and criteria that will be used for data review.

Table 2. QAPP Requirement Summary

Required QAPP Element(s) and Corresponding QAPP Section(s)	Optional QAPP Worksheet # in QAPP Workbook	Required Information
Project Management and Objectives		
2.1 Title and Approval Page	1	- Title and Approval Page
2.2 Document Format and Table of Contents 2.2.1 Document Control Format 2.2.2 Document Control Numbering System 2.2.3 Table of Contents 2.2.4 QAPP Identifying Information	2	- Table of Contents - QAPP Identifying Information
2.3 Distribution List and Project Personnel Sign-Off Sheet 2.3.1 Distribution List 2.3.2 Project Personnel Sign-Off Sheet	3 4	- Distribution List - Project Personnel Sign-Off Sheet
2.4 Project Organization 2.4.1 Project Organizational Chart 2.4.2 Communication Pathways 2.4.3 Personnel Responsibilities and Qualifications 2.4.4 Special Training Requirements and Certification	5 6 7 8	- Project Organizational Chart - Communication Pathways - Personnel Responsibilities and Qualifications Table - Special Personnel Training Requirements Table
2.5 Project Planning/Problem Definition 2.5.1 Project Planning (Scoping) 2.5.2 Problem Definition, Site History, and Background	9 10	- Project Planning Session Documentation (including Data Needs Tables) - Project Scoping Session Participants Sheet - Problem Definition, Site History and Background - Site Maps (historical and present)
2.6 Project Quality Objectives and Measurement Performance Criteria 2.6.1 Development of Project Quality Objectives Using the Systematic Planning Process 2.6.2 Measurement Performance Criteria	11 12	- Site-Specific PQOs - Measurement Performance Criteria Table
2.7 Secondary Data Evaluation	13	- Sources of Secondary Data and Information - Secondary Data Criteria and Limitations Table

Table 2. QAPP Requirement Summary (continued)

Required QAPP Element(s) and Corresponding QAPP Section(s)	Optional QAPP Worksheet # in QAPP Workbook	Required Information
2.8 Project Overview and Schedule 2.8.1 Project Overview 2.8.2 Project Schedule	14 15 16	- Summary of Project Tasks - Reference Limits and Evaluation Table - Project Schedule/Timeline Table
Measurement/Data Acquisition		
3.1 Sampling Tasks 3.1.1 Sampling Process Design and Rationale 3.1.2 Sampling Procedures and Requirements 3.1.2.1 Sampling Collection Procedures 3.1.2.2 Sample Containers, Volume, and Preservation 3.1.2.3 Equipment/Sample Containers Cleaning and Decontamination Procedures 3.1.2.4 Field Equipment Calibration, Maintenance, Testing, and Inspection Procedures 3.1.2.5 Supply Inspection and Acceptance Procedures 3.1.2.6 Field Documentation Procedures	17 18 19 20 21 22	- Sampling Design and Rationale - Sample Location Map - Sampling Locations and Methods/ SOP Requirements Table - Analytical Methods/SOP Requirements Table - Field Quality Control Sample Summary Table - Sampling SOPs - Project Sampling SOP References Table - Field Equipment Calibration, Maintenance, Testing, and Inspection Table
3.2 Analytical Tasks 3.2.1 Analytical SOPs 3.2.2 Analytical Instrument Calibration Procedures 3.2.3 Analytical Instrument and Equipment Maintenance, Testing, and Inspection Procedures 3.2.4 Analytical Supply Inspection and Acceptance Procedures	23 24 25	- Analytical SOPs - Analytical SOP References Table - Analytical Instrument Calibration Table - Analytical Instrument and Equipment Maintenance, Testing, and Inspection Table
3.3 Sample Collection Documentation, Handling, Tracking, and Custody Procedures 3.3.1 Sample Collection Documentation 3.3.2 Sample Handling and Tracking System 3.3.3 Sample Custody	26 27	- Sample Collection Documentation Handling, Tracking, and Custody SOPs - Sample Container Identification - Sample Handling Flow Diagram - Example Chain-of-Custody Form and Seal
3.4 Quality Control Samples 3.4.1 Sampling Quality Control Samples 3.4.2 Analytical Quality Control Samples	28	- QC Samples Table - Screening/Confirmatory Analysis Decision Tree

Table 2. QAPP Requirement Summary (continued)

Required QAPP Element(s) and Corresponding QAPP Section(s)	Optional QAPP Worksheet # in QAPP Workbook	Required Information
3.5 Data Management Tasks 3.5.1 Project Documentation and Records 3.5.2 Data Package Deliverables 3.5.3 Data Reporting Formats 3.5.4 Data Handling and Management 3.5.5 Data Tracking and Control	29 30	- Project Documents and Records Table - Analytical Services Table - Data Management SOPs
Assessment/Oversight		
4.1 Assessments and Response Actions 4.1.1 Planned Assessments 4.1.2 Assessment Findings and Corrective Action Responses	 31 32	- Assessments and Response Actions - Planned Project Assessments Table - Audit Checklists - Assessment Findings and Corrective Action Responses Table
4.2 QA Management Reports	33	- QA Management Reports Table
4.3 Final Project Report		
Data Review		
5.1 Overview		
5.2 Data Review Steps 5.2.1 Step I: Verification 5.2.2 Step II: Validation 5.2.2.1 Step IIa: Validation Activities 5.2.2.2 Step IIb: Validation Activities 5.2.3 Step III: Usability Assessment 5.2.3.1 Data Limitations and Actions from Usability Assessment 5.2.3.2 Activities	34 35 36 37	- Verification (Step I) Process Table - Validation (Steps IIa and IIb) Process Table - Validation (Steps IIa and IIb) Summary Table - Usability Assessment
5.3 Streamlining Data Review 5.3.1 Data Review Steps To Be Streamlined 5.3.2 Criteria for Streamlining Data Review 5.3.3 Amounts and Types of Data Appropriate for Streamlining		

It is recommended that QAPPs be identified as generic or project-specific and be prepared using the format described in this Manual. However, if some or all of the required QAPP element groups are incorporated into other project planning documents (such as SAPs, field sampling plans, field operations plans, project operations plans, or general project work plans), then a cross-reference table similar to Table 3 must be provided to identify where each required QAPP element is located in the appropriate project document. The reference should specify the complete document title, date,

section number, page numbers, and location of the information in the document. Table 3 provides an example using a fictitious project in which several elements of the project-specific QAPP are found in existing facilitywide project planning documents. This table cross-references the required QAPP element groups with information found in documents such as generic facilitywide QAPPs, SAPs, and others.

Table 3. Tracking of QAPP Requirements: Example Crosswalk to Other Project Documents

Required QAPP Element(s) and Corresponding QAPP Section(s) in UFP-QAPP Manual	Required Information	Crosswalk to Related Documents
Project Management and Objectives		
2.1 Title and Approval Page	- Title and Approval Page	
2.2 Document Format and Table of Contents 2.2.1 Document Control Format 2.2.2 Document Control Numbering System 2.2.3 Table of Contents 2.2.4 QAPP Identifying Information	- Table of Contents - QAPP Identifying Information	
2.3 Distribution List and Project Personnel Sign-Off Sheet 2.3.1 Distribution List 2.3.2 Project Personnel Sign-Off Sheet	- Distribution List - Project Personnel Sign-Off Sheet	
2.4 Project Organization 2.4.1 Project Organizational Chart 2.4.2 Communication Pathways 2.4.3 Personnel Responsibilities and Qualifications 2.4.4 Special Training Requirements and Certification	- Project Organizational Chart - Communication Pathways - Personnel Responsibilities and Qualifications Table - Special Personnel Training Requirements Table	
2.5 Project Planning/Problem Definition 2.5.1 Project Planning (Scoping) 2.5.2 Problem Definition, Site History, and Background	- Project Planning Session Documentation (including Data Needs Tables) - Project Scoping Session Participants Sheet - Problem Definition, Site History and Background - Site Maps (historical and present)	

Table 3. Tracking of QAPP Requirements: Example Crosswalk to Other Project Documents (continued)

Required QAPP Element(s) and Corresponding QAPP Section(s) in UFP-QAPP Manual	Required Information	Crosswalk to Related Documents
2.6 Project Quality Objectives and Measurement Performance Criteria 2.6.1 Development of Project Quality Objectives Using the Systematic Planning Process 2.6.2 Measurement Performance Criteria	- Site-Specific PQOs - Measurement Performance Criteria Table	
2.7 Secondary Data Evaluation	- Sources of Secondary Data and Information - Secondary Data Criteria and Limitations Table	
2.8 Project Overview and Schedule 2.8.1 Project Overview 2.8.2 Project Schedule	- Summary of Project Tasks - Reference Limits and Evaluation Table - Project Schedule/Timeline Table	Generic Facilitywide QAPP, Section 3.0
Measurement/Data Acquisition		
3.1 Sampling Tasks 3.1.1 Sampling Process Design and Rationale 3.1.2 Sampling Procedures and Requirements 3.1.2.1 Sampling Collection Procedures 3.1.2.2 Sample Containers, Volume, and Preservation 3.1.2.3 Equipment/Sample Containers Cleaning and Decontamination Procedures 3.1.2.4 Field Equipment Calibration, Maintenance, Testing, and Inspection Procedures 3.1.2.5 Supply Inspection and Acceptance Procedures 3.1.2.6 Field Documentation Procedures	- Sampling Design and Rationale - Sample Location Map - Sampling Locations and Methods/ SOP Requirements Table - Analytical Methods/SOP Requirements Table - Field Quality Control Sample Summary Table - Sampling SOPs - Project Sampling SOP References Table - Field Equipment Calibration, Maintenance, Testing, and Inspection Table	Generic Facilitywide QAPP, Volume 3 Approved Field Sampling Plan for____ Base, Pages 12-18 Approved Field Sampling Plan for____ Base, Pages 24-28 Approved Field Sampling Plan for____ Base, Pages 32-38 Generic Facilitywide QAPP, Volume 2 Approved Field Sampling Plan for____ Base, Pages 40-43

Table 3. Tracking of QAPP Requirements: Example Crosswalk to Other Project Documents (continued)

Required QAPP Element(s) and Corresponding QAPP Section(s) in UFP-QAPP Manual	Required Information	Crosswalk to Related Documents
3.2 Analytical Tasks 3.2.1 Analytical SOPs 3.2.2 Analytical Instrument Calibration Procedures 3.2.3 Analytical Instrument and Equipment Maintenance, Testing, and Inspection Procedures 3.2.4 Analytical Supply Inspection and Acceptance Procedures	- Analytical SOPs - Analytical SOP References Table - Analytical Instrument Calibration Table - Analytical Instrument and Equipment Maintenance, Testing, and Inspection Table	Generic Facilitywide QAPP, Volume 4
3.3 Sample Collection Documentation, Handling, Tracking, and Custody Procedures 3.3.1 Sample Collection Documentation 3.3.2 Sample Handling and Tracking System 3.3.3 Sample Custody	- Sample Collection Documentation Handling, Tracking, and Custody SOPs - Sample Container Identification - Sample Handling Flow Diagram - Example Chain-of-Custody Form and Seal	Approved Field Sampling Plan for____ Base, Pages 50-52 Approved Field Sampling Plan for____ Base, Pages 54-58 Approved Field Sampling Plan for____ Base, Pages 60-66 Generic Facilitywide QAPP, Section 6.1, Pages 6-4 to 6-5, Table 6-2 Generic Facilitywide QAPP, Section 6.2, Pages 6-8 to 6-9 Generic Facilitywide QAPP, Section 6.3, Pages 6-12 to 6-14, Table 6-3 Generic Facilitywide QAPP, Section 6.4, Pages 6-20 to 6-23, Table 6-4
3.4 Quality Control Samples 3.4.1 Sampling Quality Control Samples 3.4.2 Analytical Quality Control Samples	- QC Samples Table - Screening/Confirmatory Analysis Decision Tree	
3.5 Data Management Tasks 3.5.1 Project Documentation and Records 3.5.2 Data Package Deliverables 3.5.3 Data Reporting Formats 3.5.4 Data Handling and Management 3.5.5 Data Tracking and Control	- Project Documents and Records Table - Analytical Services Table - Data Management SOPs	Generic Facilitywide QAPP, Section 8, Page 8-2, Table 8-1 Generic Facilitywide QAPP, Volume 6

Table 3. Tracking of QAPP Requirements: Example Crosswalk to Other Project Documents (continued)

Required QAPP Element(s) and Corresponding QAPP Section(s) in UFP-QAPP Manual	Required Information	Crosswalk to Related Documents
Assessment/Oversight		
4.1 Assessments and Response Actions 4.1.1 Planned Assessments 4.1.2 Assessment Findings and Corrective Action Responses	- Assessments and Response Actions - Planned Project Assessments Table - Audit Checklists - Assessment Findings and Corrective Action Responses Table	Generic Facilitywide QAPP, Section 11.1, Page 11-2, Table 10-1
4.2 QA Management Reports	- QA Management Reports Table	
4.3 Final Project Report		
Data Review		
5.1 Overview		
5.2 Data Review 5.2.1 Step I: Verification 5.2.2 Step II: Validation 5.2.2.1 Step IIa: Validation Activities 5.2.2.2 Step IIb: Validation Activities 5.2.3 Step III: Usability Assessment 5.2.3.1 Data Limitations and Actions from Usability Assessment 5.2.3.2 Activities	- Verification (Step I) Process Table - Validation (Steps IIa and IIb) Process Table - Validation (Steps IIa and IIb) Summary Table - Usability Assessment	
5.3 Streamlining Data Review 5.3.1 Data Review Steps To Be Streamlined 5.3.2 Criteria for Streamlining Data Review 5.3.3 Amounts and Types of Data Appropriate for Streamlining		

Note: Table 3 represents a fictitious site created to demonstrate how to crosswalk QAPP requirements with other project documents.

1.2.5 Graded Approach

Since the content and level of detail in individual QAPPs will vary according to the work being performed and the intended use of the data, planners will want to use a "graded approach" when preparing QAPPs. A graded approach is the process of establishing the project requirements and level of effort according to the intended use of the results and the degree of confidence needed in the quality of the results. **In other words, the degree of documentation, level of effort, and detail will vary based on the complexity and cost of the project.** Appropriate and objective consideration should be given to the significance of the environmental problems to be investigated, the environmental decisions to be made, and the impact on human health and the environment. Documentation will consist of a concise explanation whenever the particular project does not need to address a specific area. In addition, by cross-referencing to approved generic QAPPs, project-specific QAPPs may need less detail in certain areas. Throughout the remainder of the document, examples of the graded approach are provided in text boxes.

1.2.6 Review and Approval of QAPPs

Depending on the nature of the QAPP, the environmental program it implements, and various enforceable agreements, QAPP review and approval may be required by several different entities. This section discusses:

- Review and approval of QAPPs within the lead organization
- Regulatory review and approval of QAPPs

The following sections also present a timeline for the review, implementation, and record archival of a QAPP that also shows the needed lead-time for review, approval and implementation. This timeline is presented as follows:

<u>Review and Approval of QAPPs (Section 1.2.6.1)</u> – Organization personnel, contractors, subcontractors review before regulatory approval authority submittal
<u>Regulatory Review and Approval of QAPPs (Section 1.2.6.2)</u> – Submitted to regulatory authority at least 30 days in advance of scheduled data collection
<u>QAPP Implementation and Modification (Section 1.2.7)</u> – Verbal authorization of modification documented; Amendment to QAPP within 7 working days for signature approval
<u>QAPP Annual Review (Section 1.2.7)</u> – One year from the date the QAPP was approved
<u>QAPP Revision at Least Every 5 Years (Section 1.2.7)</u>
<u>QAPP Archival (Section 1.2.8)</u> - Reviewer's Comments and Responses

1.2.6.1 <u>Lead Organization Review and Approval</u>

The QAPP should undergo internal review at all appropriate levels. The lead organization is responsible for ensuring that the QAPP is accurate and complete, that it conforms to the

requirements stated in this UFP-QAPP Manual, and that all project quality objectives (PQOs), technical activities, and related QA/QC will result in data of known and documented quality. To that end, the lead organization should require that organizational personnel, contractors, and subcontractors review applicable sections of the QAPP prior to submitting it to EPA or other regulatory approval authority.

1.2.6.2 Regulatory Review and Approval of QAPPs

It is EPA policy that a QAPP be reviewed and approved prior to initiation of fieldwork. The type of regulatory review and approval required is project-specific. In many instances, requirements for such review and approval will be specified in legal agreements. EPA is responsible for reviewing and approving all CERCLA QAPPs, except in cases where the review and approval authority has been delegated by EPA to a non-EPA partner organization such as a State, Tribe, or other Federal department, agency, or program, or where EPA has chosen not to review QAPPs for sites not on the National Priorities List (NPL). EPA's delegation of this authority to a non-EPA organization is contingent on that organization having an acceptable quality system documented in an EPA-approved Quality Management Plan (QMP).

All QAPPs and related documents subject to regulatory approval are reviewed to ensure that they are complete, are technically adequate, and meet the requirements of this UFP-QAPP Manual. The QAPP is reviewed to ensure that PQOs, technical activities, and related QA/QC will result in data of known and documented quality that can be used in environmental decision-making. Review and approval of QAPPs by EPA and EPA-delegated approval authorities must be in accordance with requirements of this UFP-QAPP Manual. States, Tribes, and other Federal departments, agencies, or programs are encouraged to use this Manual when reviewing and approving QAPPs. Although the format established in the Manual and worksheets is not required, it will facilitate review by the approval authority.

When developing generic QAPPs that will apply across multiple EPA Regions or regulatory approval authorities, the scoping process must involve those entities early in the development of the QAPP. Receiving input early will help streamline review and approval of the generic QAPP.

All comments provided by EPA or the approval authority must be acceptably addressed in writing prior to beginning field activities. The response document (either a revised QAPP or a letter responding to specific deficiencies) should contain complete identifying information as it is presented on the original QAPP. Any revisions to the original QAPP should be identified to expedite document review and approval.

1.2.7 QAPP Implementation and Modification

The approved QAPP must be implemented as prescribed; however, the implementation process is intended to be flexible and nonrestrictive. If an approved QAPP must be altered in response to project needs (including changes to project team members), the amended QAPP must be reviewed

and approved by the original approval authority in the same manner as the original QAPP. The amendment must contain complete identifying information, as presented on the original QAPP Title and Approval Page, with updated signatures and dates. Only after the amendment has been approved can the change be implemented.

Verbal or electronic approval of modifications may be obtained to expedite project work. Verbal approvals should be documented in telephone logs. Both verbal and electronic approvals should be retained in the project file. Subsequently, the approved modification must be documented in an amendment to the QAPP and submitted to EPA (or other approval authority, if applicable) for signature approval within 7 working days.

Corrective actions must be implemented when deviations from the QAPP are noted by project personnel outside of the formal assessment process. Corrective actions need to be initiated whenever project personnel identify field sampling or analytical problems that could potentially affect data quality or usability. Such incidents should be documented and resolved using the procedures and personnel for planned assessments described in the QAPP (see Section 4.1.2).

Both project-specific and generic QAPPs should be reviewed annually by the lead organization's project manager. Project-specific and generic QAPPs must be kept current and be revised when necessary, when directed by the approval authority, or at least every 5 years.

1.2.8 QAPP Archiving

All QAPPs, including reviewers' comments and responses to reviewers' comments (revised QAPPs or response letters addressing specific issues), must be archived in the appropriate project or program file according to the procedures specified by the lead organization in its QAPP or QMP.

Project files must be retained for the period of time specified in the interagency agreement, MOU, cooperative agreement, financial agreement, contract, or voluntary or enforcement consent decree, agreement, or order.

1.3 Roles and Responsibilities

1.3.1 Lead Organization

The lead organization for environmental data collection operations, as defined by this UFP-QAPP Manual, will be a Federal department, agency, or program and will usually be the entity that owns the facility or installation where work is being done. The lead organization is responsible for all phases of environmental data collection, as well as for ensuring that organization personnel, contractors, and subcontractors perform project work as prescribed in the approved QAPP. The lead organization may perform the project work directly or contract for field sampling, analytical services, or data review.

1.3.2 Project Manager

The project manager is responsible for directing or overseeing and coordinating all project activities for the lead organization, including assembling a project team (see Section 1.3.3). He or she is responsible for submitting QAPPs and QAPP revisions and amendments to appropriate personnel for review and approval.

The project manager must ensure that all technical issues identified during QA review are satisfactorily addressed and documented prior to beginning the data collection activity. The project manager is also responsible for reviewing the QAPP annually and documenting this review in a letter to the approval authority.

Note: QAPPs should be submitted to the approval authority for review and approval no less than 30 days in advance of the scheduled environmental data collection or in whatever time period is specified by project-specific agreements (e.g., MOU, Federal facilities agreement, permits). All QAPP revisions and amendments should be submitted in a timely way, so that the approval authority has sufficient time to complete the review and approval process prior to the collection of environmental data.

1.3.3 Project Team

The project team consists of technical personnel, including data generators, QA scientists, and data users (e.g., geologists, chemists, risk assessors). The project team may include contractors and subcontractors. The size and makeup of the project team should reflect the size, complexity, and needs of the project. For example, small projects may have project teams that consist of only two or three people (a situation for which the graded approach may be appropriate). Individuals responsible for the following tasks are critical to the success of the project and should be selected as project team members by the lead organization: project management, health and safety, field mobilization, sampling, geotechnical operations, sample analysis, QA activities (including field and laboratory assessment), data review, and risk assessment.

During planning (scoping), the project team identifies project and data quality objectives, decisions to be made, project "action limits," the type and quantity of data, and how "good" the data must be (the data quality) to ensure that scientifically defensible environmental decisions are made. The project team defines the quality of the data by setting acceptance limits for the projects to meet the project quality objectives (PQOs). Once the acceptance limits, also known as measurement performance criteria have been decided on, the project team can select sampling and analytical methods that have appropriate quantitation limits and QC limits to achieve project objectives.

The project team is responsible for providing all the information required by this UFP-QAPP Manual and for resolving all technical issues prior to QAPP preparation. Ultimately, it is the responsibility of the project team (not the QAPP preparer) to design a QA "blueprint" that meets project objectives.

1.3.4 QAPP Preparation Team/Writer

The QAPP should be written by a team or individual that has been involved in the project planning phase and has experience or training with QAPP preparation. Members of the QAPP preparation team should be experienced in many aspects of environmental science, including chemistry, engineering, hydrogeology, and risk assessment. In addition, the QAPP preparation team should be experienced with the sample collection procedures, analytical methods, and data review procedures that will be used for the project.

1.3.5 Project Personnel

An organizational chart must clearly show the reporting relationships among all of the lead organization's project personnel, including contractors and subcontractors.

All project personnel are responsible for reading and understanding applicable sections of the QAPP before beginning fieldwork. All individuals who have project responsibilities should sign a Project Personnel Sign-Off Sheet to document that they have read all relevant portions of the QAPP.

All project personnel are responsible for implementing the QAPP as prescribed, and for reporting all deviations from the QAPP to the project manager. Corrective action procedures must be implemented when deviations from the QAPP are noted or whenever project personnel identify field sampling or analytical problems that could potentially affect data quality or usability.

2.0 PROJECT MANAGEMENT AND OBJECTIVES ELEMENTS

The project management and objectives elements of a QAPP ensure that the project has a defined purpose by documenting the environmental problem, the environmental questions being asked, and the environmental decisions that need to be made. The elements in this part of the QAPP identify the project quality objectives necessary to answer those questions and support those environmental decisions. They also address management considerations, such as roles and responsibilities, for the project.

QAPP Worksheets

The following sections provide a comprehensive list of the information required in a QAPP. As much as possible, this information should be presented in tabular format for ease of review. However, sufficient written discussion in text format should accompany all tables. To assist with this process, worksheets for optional use are provided in Part 2A of the UFP-QAPP, the QAPP Workbook. In addition, examples of QAPPs developed for different programs are available in Part 2C of the UFP-QAPP, and examples of selected worksheets are presented throughout this Manual. Although the examples are from typical chemical sampling and analysis projects, worksheets can and should be modified to reflect project-specific requirements and address the type of investigation (e.g., radiochemical, biological, ordnance and explosives).

2.1 Title and Approval Page

The Title and Approval Page is the first page of the QAPP. It documents that the QAPP has received proper regulatory approval prior to implementation.

The Title and Approval Page should contain the required approval signatures and other information shown below. (Note: In the QAPP Workbook, this information corresponds with QAPP Worksheet #1.)

- Site name/project name
- Site location
- Document title
- Lead organization (see Section 1.3.1)
- Preparer's name and organizational affiliation
- Preparer's address, telephone number, and e-mail address
- Preparation date (day/month/year)

- Investigative organization's project manager's signature and printed name/organization/date[2]
- Investigative organization's project QA officer's signature and printed name/organization/date
- Lead organization's project manager's signature and printed name/organization/date
- Appropriate approval signatures and printed names/titles/dates

2.2 Document Format and Table of Contents

The organization of the QAPP should be easy to understand and should follow the format and section headings as described in this UFP-QAPP Manual to expedite review. All tables, diagrams, charts, worksheets (if used), and other deliverables, which are itemized in this Manual, should be included as components of the QAPP and listed in the Table of Contents. Any required QAPP element groups that are not applicable to the project should be identified either on the QAPP Requirements Summary table (Table 2 in Section 1.2.4) or in some other format provided by the QAPP preparer, along with a justification for their exclusion.

2.2.1 Document Control Format

Document control procedures are used to identify the most current version of the QAPP and to ensure that only that version of the QAPP is used by all project participants.

The QAPP preparer should use a consistent document control format (e.g., in the upper right-hand corner of each page of the document) to present the following information:

- The title of the document (abbreviations may be used).
- The original version number or revision number, whichever is applicable, including document status (i.e., draft, interim draft, interim final, final).
- The date of the original version or current revision, whichever is applicable.
- The page number in relation to the total number of pages. Alternatively, pages may be numbered as part of the total pages for a discrete section. (In the case of the second option, the Table of Contents should list inclusive page numbers for each subsection, e.g., 1-1 through 1-9).

The document control procedures should be applied to the QAPP beginning on the Title and Approval Page and including the Table of Contents and all figures, tables, and diagrams. Each revision of the QAPP should be differentiated by a new revision number and date.

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[2]The investigative organization is an entity contracted by the lead organization for one or more phases of a data collection operation.

2.2.2 Document Control Numbering System

A document control numbering system accounts for all copies of the QAPP provided to project personnel and helps to ensure that the most current version is in use. A sequential numbering system is used to identify controlled copies of the QAPP. Controlled copies should be assigned to individuals within an organization or team. Individuals receiving a controlled copy of the QAPP are provided with all revisions, addenda, and amendments to the QAPP. Individuals who receive a controlled copy are responsible for removing all outdated material from circulation.

> **Graded Approach**
>
> The use of a document control numbering system may not always be necessary, such as for small projects or projects that do not require the distribution of copies across multiple organizations.

The document control system does not preclude making and using copies of the QAPP; however, holders of controlled copies are responsible for distributing revised or added material to update any copies within their organizations. The distribution list for controlled copies should be maintained by the organization that prepares the QAPP, and a copy of that distribution list should be provided to the lead organization.

2.2.3 Table of Contents

A Table of Contents clearly outlines the organization of the QAPP and makes project information easy to reference. The QAPP should include a Table of Contents that is comprehensive and contains the title and location (i.e., page number, appendix or attachment number) of the following items:

- Major sections
- Subsections
- References
- Appendices and/or attachments (e.g., SOPs)
- Tables
- Figures
- Diagrams

> **References**
>
> The reference section of this Manual lists applicable national requirements and guidance documents. Web site addresses are noted for most documents.

> **Note:** Applicable appendices and/or attachments include but are not limited to the following:
> - SOPs for sampling, drilling, sample preparation and analysis, etc., that are included as attachments
> - The completed QAPP worksheets, if the QAPP worksheets are used and not included as tables in the QAPP
> - Laboratory quality assurance plans or quality assurance manuals for participating laboratories

2.2.4 QAPP Identifying Information

The QAPP identifying information prefaces the content of the QAPP and places the document in context for the reviewer. It identifies the key project players, previous site work, if any, and the program for which the current project is being performed. QAPP identifying information should be consolidated in one table (QAPP Worksheet #2). The identifying information required includes:

- Site name/project name
- Site location
- Site number/code
- Operable unit
- Contractor name
- Contractor number
- Contract title
- Work assignment number
- Guidance used to prepare QAPP
- Regulatory program (e.g., RCRA, CERCLA, Clean Water Act)
- Approval entity
- Data users
- Identification as a generic or project-specific QAPP
- Scoping session dates

Additional information that may be presented includes:

- Dates and titles of QAPP documents written for previous site work
- Organizational partners (stakeholders) and connection with lead organization
- QAPP element groups and required information not applicable to this project (Exclusions can be identified in QAPP Worksheet #2 and described in the text.)

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QAPP Worksheet #2, equivalent to Table 3 in Section 1.2.4, may be used to identify opportunities for the graded approach.

2.3 Distribution List and Project Personnel Sign-Off Sheet

2.3.1 Distribution List

The Distribution List documents those entities to whom copies of the approved QAPP and any subsequent revisions will be sent. (See Figure

Graded Approach

In those cases where the QAPP will have a limited distribution, such as within a single facility, a simple sign-out sheet could be sufficient.

3 and QAPP Worksheet #3.) A complete copy of the QAPP should be sent to the project manager and key project personnel for the lead organization and to EPA or the delegated approval authority. Key project personnel are those working for the lead organization, including contractors and subcontractors. Examples include the lead field sampler, project manager, data reviewer, statistician, risk assessor, assessment personnel, and laboratory QC manager. In addition, a complete copy of the original version and all revisions of the QAPP, including addenda and amendments, should be maintained on file by the lead organization and made available to approval authorities upon request. The distribution list may change and should be revised for each QAPP revision submitted. Each revision of the QAPP should contain the information shown in Figure 3.

QAPP Recipients	Title	Organization	Telephone Number	Fax Number	E-mail Address	Document Control Number

Figure 3. Distribution List
(QAPP Worksheet #3)

Note: Examples of select worksheets that are complicated and require additional information are provided throughout this Manual to help the reader understand their intended content. Worksheets that are self-explanatory do not include examples, only table headings.

2.3.2 Project Personnel Sign-Off Sheet

The Project Personnel Sign-Off Sheet documents that all key project personnel performing work have read the applicable sections of the QAPP and will perform the tasks as described. For example, the laboratory manager who receives the QAPP should have all supervisory personnel sign off on the applicable analysis sections of the QAPP before beginning sample analysis. Supervisory or oversight personnel are responsible for communicating the requirements of the applicable portions of the QAPP to those doing work. Although it is not always possible to identify people by name early in the planning stages, the project team should identify by function (e.g., laboratory QC manager) all personnel who are to read and sign off on the applicable sections of the QAPP. Figure 4 (QAPP Worksheet #4) shows what information to include in the original QAPP and all revisions.

Project Personnel	Title	Telephone Number	Signature	Date QAPP Read

Figure 4. Project Personnel Sign-Off Sheet
(QAPP Worksheet #4)

2.4 Project Organization

The project team should identify the reporting relationships between the organizations, project team members, and other key project personnel and describe their specific roles, responsibilities, and qualifications. In addition, the QAPP text should include an explanation of the lines of authority and paths of communication.

2.4.1 Project Organizational Chart

The Project Organizational Chart shows reporting relationships between all organizations involved in the project, including the lead organization and all contractors and subcontractors. Project team members should identify the organizations providing field sampling, on-site and off-site analysis, and data review services, including the names and telephone numbers of all project managers, project team members, and project contacts for each organization. See Section 1.3.3 of this Manual for a discussion of the project team. The types of information required in an organizational chart are shown in Figure 5 (QAPP Worksheet #5).

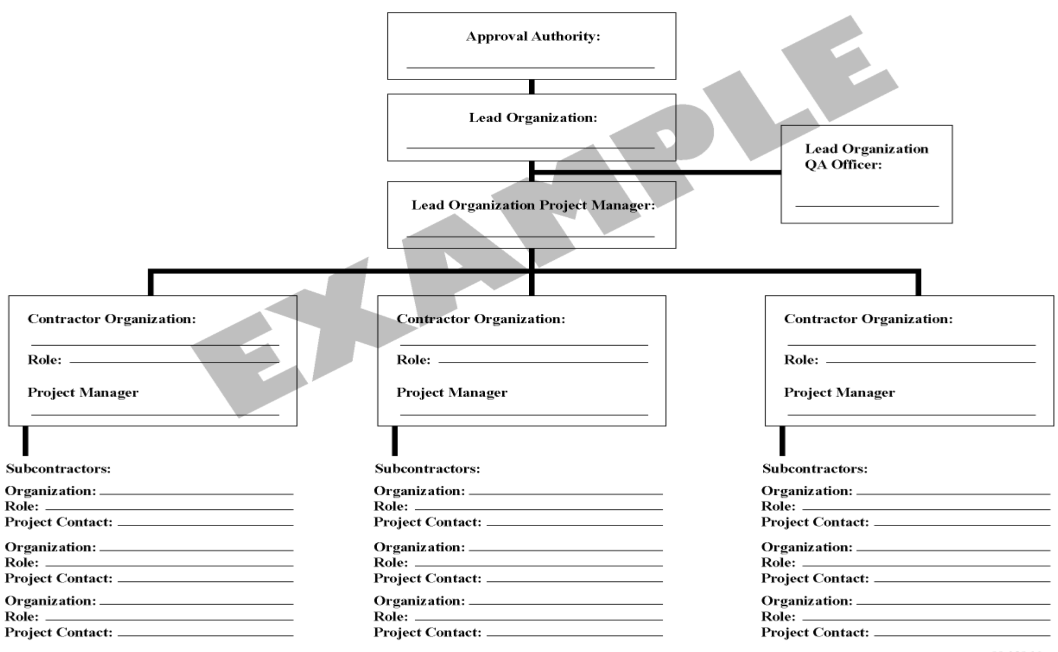


Figure 5. Example Project Organizational Chart (QAPP Worksheet #5)

Graded Approach

Generally, for smaller, less complex projects, the organizational chart will be considerably smaller. Project personnel may be assigned multiple responsibilities. However, in all cases the QA officer should be independent of data collection activities.

2.4.2 Communication Pathways

One of the keys to a successful project is communication. Communication pathways and modes of communication (faxes, newsletters, electronic mail, reports) should be delineated in the project planning stage and documented in the QAPP. These pathways include the points of contact for resolving sampling and analysis problems and for distributing preliminary, screening, and definitive data to managers, users, and the public. The project team should describe the proper procedures for soliciting concurrence and obtaining approval between project personnel, between different contractors, and between samplers and laboratory staff. Figure 6 (QAPP Worksheet #6) may be used to capture these communication pathways.

Communication Drivers	Responsible Entity	Name	Phone Number	Procedure (Timing, Pathways, etc.)

Figure 6. Communication Pathways
(QAPP Worksheet #6)

Communication drivers are those activities that necessitate communication between different responsible entities. These drivers can include, but are not limited to:

- Approval of amendments to the QAPP
- Initiation, notification and/or approval of real time modifications
- Notification of delays or changes to field work
- Recommendations to stop work and initiation of corrective action
- Reporting of issues related to analytical data quality, including, but not limited to, ability to meet reporting limits

Responsible entities are the project personnel that may be responsible for initiating, communicating, or approving one of the communication drivers. Example responsible entities include, but are not limited to:

- Regulatory approval authority
- Lead organization project manager

- Contracting officer representative
- Lead organization QA officer
- Field sampling project manager
- Field sampling QA officer
- Health and safety officer
- Laboratory project manager
- Laboratory QA officer

Procedures (timing, pathways and types of acceptable communications) must be outlined in sufficient detail to ensure that users of the QAPP understand the processes and the roles and responsibilities associated with those processes when communication is necessary. Issues that should be addressed include, but are not limited to:

- Who may approve specific types of real time modifications, including who will be notified and the timing of such notification
- Nature of required communication forms (e.g. electronic, verbal, written)
- Processes and authorities for recommending work stoppage and corrective action.

The following statements are examples of communication processes that may be documented as procedures in QAPP Worksheet #6:

- If field sampling will be delayed, then the project manager from the field sampling contractor organization will notify____.
- No data may be released to the public until ____.
- If the laboratory fails to accurately analyze a proficiency testing (PT) sample, then the project manager from the lead organization will____.

The project team also should document the procedures that will be followed when any project activity originally documented in an approved QAPP requires real-time modification to achieve project goals. These project activities include, but are not limited to:

- Sampling design
- Sample collection procedures
- Sample analysis procedures
- Data review and reporting

All significant QAPP modifications must be documented and submitted for approval in accordance with the original QAPP (see Section 1.2.7). The person requesting a modification and the person who must approve the modification, and the rationale for the modification must be documented. All changes, including minor changes or changes dictated by field conditions, must be reported to approving organizations and documented.

The project team also should describe the procedures for initiating modifications to project activities, name the individual who has the authority to initiate procedural modifications, and describe how amendments to the QAPP will be documented and submitted to EPA, or the delegated authority, for approval. All amendments must be included with the final version of the QAPP that is maintained by the lead organization as part of the official project records.

The QAPP should spell out the difference between a modification and a one-time deviation, and between a significant deviation and one considered minor. All deviations and the reasons for them must be documented in writing and incorporated into the project files. In the case of a time-sensitive issue, verbal or electronic approval for the change may be given; however, any such change must subsequently be documented in writing and included in the project files. The QAPP must specify who has the authority to request and to issue verbal or electronic approvals for modifications or one-time deviations from the approved QAPP.

2.4.3 Personnel Responsibilities and Qualifications

Project personnel in responsible roles may include both prime contractors and subcontractors. Project personnel's responsibilities and qualifications can be presented in a table identifying project team members. Resumes for each person identified should be attached to the QAPP or their location noted. Figure 7 (QAPP Worksheet #7) shows what information to include in each revision of the QAPP. The lead organization must ensure that the responsible project personnel meet any specific QAPP qualifications, such as laboratory certification or professional engineer (PE).

The table should include the name, title, and affiliation of the following:

> **Graded Approach**
>
> The actual requirements for responsible project personnel depend on the complexity, type, and size of the project. For example, requirements for a sampling technician for a routine compliance project may be quite different from the requirements for a technician collecting samples that may be used in a complex Superfund risk assessment project.

- Data users – Technical personnel who use the collected data to perform their responsibilities (e.g., risk assessment, remedial design, legal compliance).
- Decision-makers – Individuals who will make decisions based on the collected data.
- Lead organization's project manager – Individual with the responsibility and authority to allocate resources and personnel to accomplish the project tasks as documented in the QAPP.
- Lead organization's quality assurance officer – Individual who provides QA oversight of project activities and who works independently of those performing project tasks.
- Project manager(s) and/or project contact(s) for other organizations involved in the project.
- QA manager or officer or QA contact for other organizations involved in the project – Individual responsible for checking that correct procedures are used; is independent of the group performing the task; has the authority to initiate a work stoppage to correct quality concerns.

- Project health and safety officer – Individual certified in health and safety; has the authority to initiate a work stoppage due to health and safety concerns.
- Geotechnical engineers and hydrogeologists.
- Field operation personnel, including field sampling coordinator, drillers, direct-push technology operators (Geoprobes, Cone Penetrometers), and field sampling personnel.
- Analytical services, including on-site analytical support and off-site laboratory services.
- Data reviewers.

Name	Title	Organizational Affiliation	Responsibilities	Education and Experience Qualifications

Figure 7. Personnel Responsibilities and Qualifications (QAPP Worksheet #7)

2.4.4 Special Training Requirements and Certification

Certain projects may require uniquely trained personnel to perform specialized field reconnaissance, sampling, on-site or off-site analysis, data review, and other project functions. All project personnel must be qualified and experienced in the project tasks for which they are responsible. A table showing any specialized training needed to achieve project objectives can be provided. Training records and/or certificates should be attached to the QAPP, or their location noted. If training records or certificates do not exist or are unavailable, this should be noted in the QAPP. Figure 8 (QAPP Worksheet #8) shows what information to include in the Special Personnel Training Requirements table.

Project Function	Specialized Training – Title or Description of Course	Training Provider	Training Date	Personnel/ Groups Receiving Training	Personnel Titles/ Organizational Affiliation	Location of Training Records/Certificates

Figure 8. Special Personnel Training Requirements (QAPP Worksheet #8)

2.5 Project Planning/Problem Definition

To ensure QAPP approval, the QAPP should provide a regulatory, programmatic, and historical context for the project and convey to the reviewer a clear understanding of the project background and environmental problems that exist. The QAPP must address project planning, identify the environmental problem, define the environmental questions that need to be answered, and provide background information.

2.5.1 Project Planning (Scoping)

Project scoping is key to the success of any project. Scoping defines the purpose and expected results of the project; the environmental decisions that need to be made; the project quality objectives necessary to achieve expected results and support environmental decisions; the sampling, analytical, and data review activities that will be performed; and the final products and deliverables for the project. Prior to QAPP preparation, the project team should hold one or more scoping sessions. The QAPP should document all project planning sessions held during the initial planning phase.

If the project team is using worksheets from the QAPP Workbook, the worksheets should be completed at the initial scoping session using as much information as is available. The worksheets should be finalized at subsequent sessions and included as tables, diagrams, and figures in the QAPP. The QAPP should include explanatory text for tables, figures, and diagrams whenever necessary. If the worksheets are not used, the project team members must produce a QAPP that addresses the information required by this UFP-QAPP Manual (see Table 3). Alternatively, the project team may create or modify the worksheets in the Workbook to meet their specific needs.

Other worksheets that focus on the data user's perspective may be used during the scoping sessions. Examples for compliance, remedy, and risk assessment scenarios are shown in Figures 9 through 11. (These examples were adapted from USACE Manual No. 200-1-2, *Technical Project Planning Process*, August 31, 1998, Appendix F.) Using additional worksheets will help prepare data users for the scoping session and focus the planning on the most appropriate sampling and analytical strategy to obtain the data needed to support the project's environmental decisions.

> **Note:** The following example worksheets are not included in the QAPP Workbook because they illustrate specific user needs that will not always be applicable. They are presented here as a demonstration of the kinds of additional worksheets that may be useful.

Scoping session participants should be documented in the QAPP or in the project file and should include project managers, data generators (including sampling and laboratory analysis personnel), data reviewers, quality assurance personnel, data users, and all other stakeholders. The project team members who are responsible for planning the project should be identified. Figure 12 (QAPP Worksheet #9) shows what information to include in the Project Scoping Session Participants Sheet.

> **Graded Approach**
>
> Note that the type and frequency of scoping sessions and the type and number of persons who participate in scoping sessions are related to the size and complexity of the project, the technical components of the project, and the number of organizations involved. For example, small projects may use project teams that consist of only two or three people and convene via teleconference.

Data Need		Data Use(s)		Number or Frequency of Samples	Compliance Reference Concentration	Point(s) of Compliance/Sample Location(s) and Depth
Target Analyte	**Matrix**	**Regulatory Program or Statute and Citation**	**Specific Use**			
Chromium, Cr	Soil	RCRA 40 CFR 261.24	Determine if IDW is hazardous waste.	1 composite sample per rolloff container	5.0 mg/L (TCLP Cr)	Representative sample of waste stream (soil).
Total Chromium, Cr	GW	RCRA 40 CFR 261.24		1 sample per drum	5.0 mg/L (Total Cr)	Representative sample of waste stream (purge water).
Chromium, Cr III	Water	CWA 40 CFR 131	Determine if treatment plant effluent requires pretreatment prior to discharge to surface water.	1 sample (timeframe is to be determined)	180 Fg/L	Groundwater treatment plant effluent at point source discharge location.
Chromium, Cr VI	Water	CWA 40 CFR 131		1 sample (timeframe is to be determined)	10 Fg/L	Groundwater treatment plant effluent at point source discharge location.
Chromium, Cr	GW	SDWA 40 CFR 141	Determine if GW concentrations exceed maximum contaminant levels.	1 per well	0.1 mg/L	Required at the point-of- use tap, but sampling at monitoring wells is adequate.

Figure 9. Example Data Needs Worksheet – Compliance Perspective

Data Need		Data Use(s)				
Target Analyte or Characteristic of Interest	**Matrix**	**Remedy Method(s) of Interest**	**Criteria to be Considered**	**Number or Frequency of Samples**	**Concentration of Interest or Sensitivity of Measurement(s)**	**Remediation Area(s)/ Sample Location(s) and Depth**
Vinyl chloride	Air	Air stripping	Effectiveness control	3 over 3-day operating period	2.0 gm/hr	At stack emissions after air stripper.
Depth to bedrock	Soil	Slurry wall	Implementability and conceptual cost estimate	1 location every 100 ft.	Measurements should be within +/- 1 ft.	Along planned alignments of slurry wall and treatment wall as shown on attached figure.
		Treatment wall		1 location every 25 ft.		
Hydraulic conductivity, grain size distribution, and porosity	GW	Treatment wall	Effectiveness, implementability, and conceptual cost estimate	5	ASTM, +/- 0.1%	Preferred locations distributed along middle of planned alignment of treatment wall.
Lead and cadmium	Soil	Off-site disposal	Removal action estimate of transportation and disposal costs	Composite 1 per 100 cubic yards of stockpiled soils	TCLP	Random, composite samples from within each stockpiled soil pile (i.e., BV2, BV4, BV7-9, and BV12) on the attached figure.
pH, total dissolved solids, and total organic carbon	SW	On-site water treatment by electrochemical precipitation or ion exchange	Effectiveness, implementability, cost, and O&M	5	pH within +/- 0.5, TDS and TOC within +/- 0.5 mg/L	Surface water samples halfway down water column; 2 in the center of basin 15, and 3 along the edges.

Figure 10. Example Data Needs Worksheet – Remedy Perspective

Data Need		Data Use(s)			Number of Samples	Risk Action Level(s)		Exposure Area(s)/ Sample Location(s) and Depth
Target Analyte	**Matrix**	**Current or Future Use**	**Receptor Group(s)**	**Receptor's Exposure Route (s)**		**Human Health**	**Ecological**	
Vinyl chloride	GW	Current use	Industrial workers	Incidental ingestions, dermal, and inhalation	20	N/A	N/A	The two worst-case downgradient wells found during PA/SI.
Vinyl chloride	GW	Future use	Residents	Incidental ingestions, dermal, and inhalation	20	0.019 Fg/L (RBC)	N/A	The two worst-case downgradient wells found during PA/SI.
Lead and cadmium	Soil	Current use	Industrial workers	Ingestion and dermal	20	1,000 mg/kg	N/A	Within area outlined on attached figure and at 0-24 inches.
Lead and cadmium	Soil	Future use	Residents	Ingestion and dermal	20	400 and 39 mg/kg	0.1 and 2.5 mg/kg	Within area outlined on attached figure and at 0-24 inches.

Figure 11. Example Data Needs Worksheet – Risk Assessment Perspective

<table>
<tr><td colspan="2">Project Name:
Projected Date(s) of Sampling:
Project Manager:</td><td colspan="4">Site Name:
Site Location:</td></tr>
<tr><td colspan="6">Date of Session:
Scoping Session Purpose:</td></tr>
<tr><th>Name</th><th>Title</th><th>Affiliation</th><th>Phone #</th><th>E-mail Address</th><th>Project Role</th></tr>
</table>

Figure 12. Project Scoping Session Participants Sheet
(QAPP Worksheet #9)

2.5.2 Problem Definition, Site History, and Background

The QAPP should frame, for the reader or reviewer, the reasons for conducting the project, including historical information, current site conditions, and other existing data applicable to the project. This information can be used to clearly define the problem and the environmental questions that should be answered for the current investigation, as well as to develop the project "If..., then..." statements in the QAPP, linking data results with possible actions.

The following information should be summarized in the text of the QAPP or presented in QAPP Worksheet #10:

- **The problem to be addressed by the project.** For example, "Residential drinking water wells in Toadville have shown increasing levels of benzene over the past two years."

- **The environmental questions being asked.** For example, "What is the source of the benzene contamination in the residential drinking water wells of Toadville, NH?"

- **Observations from any site reconnaissance reports.** Information about pertinent existing site conditions (e.g., evident soil staining and the presence of free product materials, odors, and other known hazards) should be identified and their location specified. Physical objects (e.g., metallic debris, drums, dilapidated buildings, processing equipment, and known safety hazards) also should be identified and their location specified.

- **A synopsis of secondary data or information from all site reports.** Existing reports (e.g., monitoring reports and remedial investigation/remedial action reports) that describe site conditions and indicator chemicals for long-term remediation or monitoring projects should be cited. Refer to Section 2.7 for a complete discussion of the identification and use of data acquired from secondary sources.

- **The possible classes of contaminants and the affected matrices.** The past and current chemical use information will be the basis for deciding the target analytes/contaminants of concern to be investigated during the project. Information to consider includes historical site usage, site neighbors, industrial processes, process by-products, waste disposal practices, and possible contaminant breakdown products.

- **The rationale for inclusion of chemical and nonchemical analyses.**

- **Information concerning various environmental indicators.** These indicators describe the present condition of the environment (e.g., water, soil, sludge, sediment, air, and biota) and provide a benchmark to monitor changes in the condition of the environment.

Additionally, the following site maps and/or figures should be provided in the QAPP, as available:

- A detailed site map that shows the site in its present state and specifies its boundaries
- A map that places the site in geographical context
- Historical maps or plans of the site prior to the investigation
- Maps identifying past and planned sampling locations
- Historical and current aerial photographs

An 8½" x 11" copy of all site maps and drawings should be included in the QAPP in addition to larger foldout maps and drawings.

2.6 Project Quality Objectives and Measurement Performance Criteria

The QAPP must document the environmental decisions that need to be made and the level of data quality needed to ensure that those decisions are based on sound scientific data.

2.6.1 Development of Project Quality Objectives Using the Systematic Planning Process

Project quality objectives (PQOs) define the type, quantity, and quality of data that are needed to answer specific environmental questions and support proper environmental decisions. The project team should determine and agree on PQOs during the initial scoping sessions using a systematic planning process. A team can develop acceptance or performance criteria specific to the type, quality, and quantity of the data needed for the decision that is to be made. Figure 13 diagrams a systematic planning process. Although the activities presented in Figure 13 are sequential, the planning process is iterative and project planners are advised to revisit relevant activities whenever necessary.

The systematic planning process is based on the scientific method and includes concepts such as objectivity of approach and acceptability of results. It uses a commonsense graded approach to ensure that the level of detail in planning is commensurate with the importance and intended

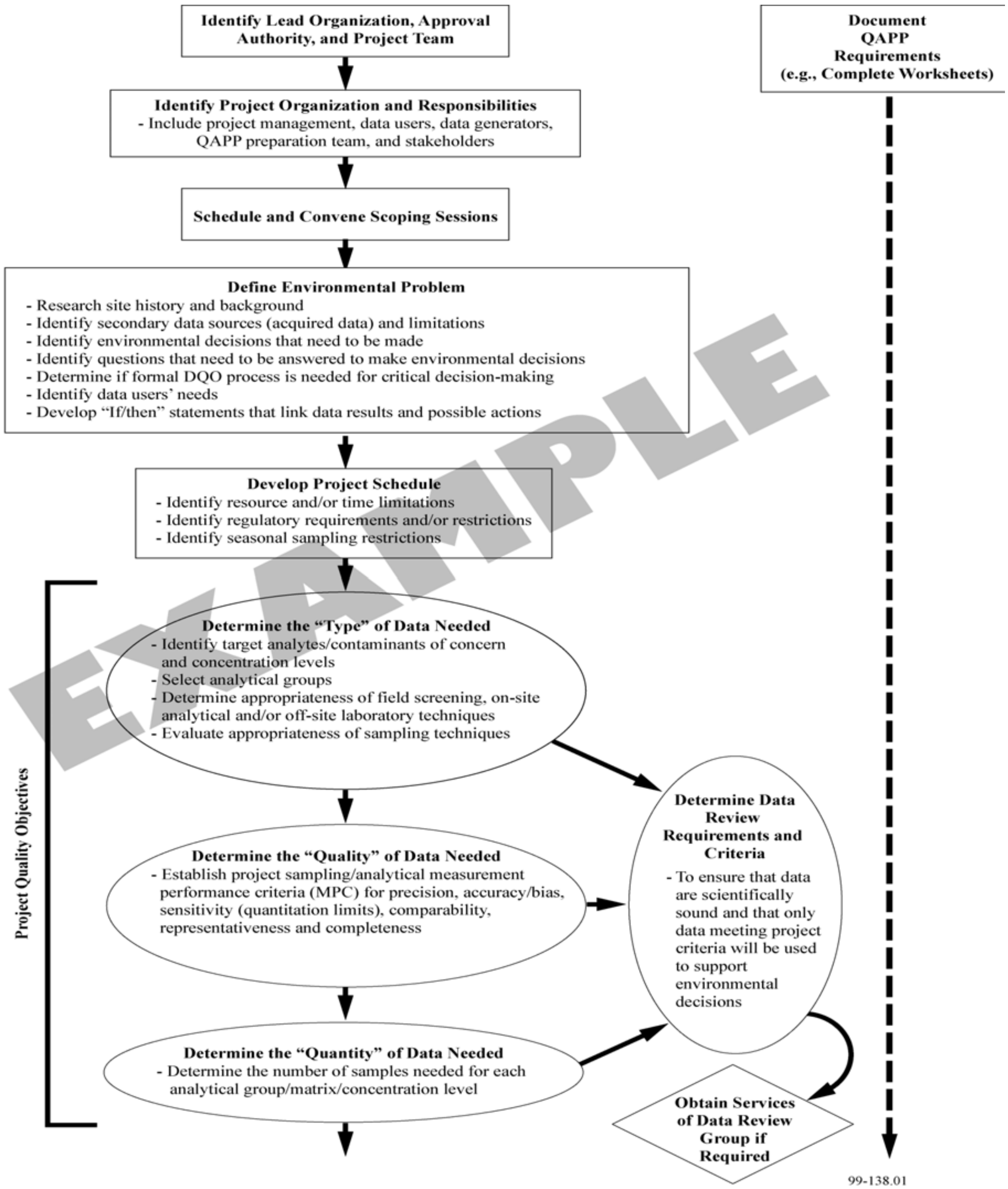


Figure 13. Systematic Planning Process

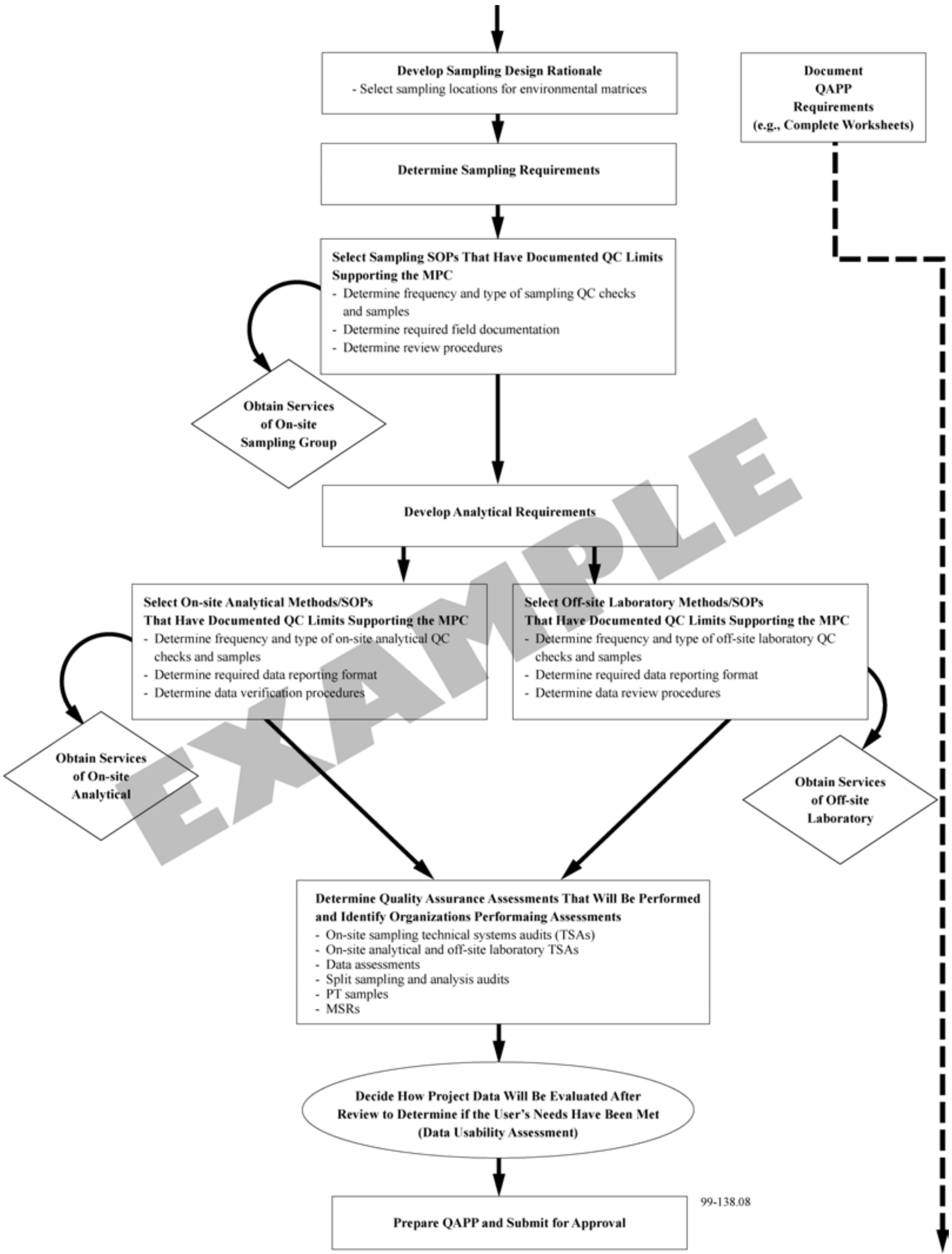


Figure 13. Systematic Planning Process (continued)

purpose of the work and the use of available resources. This framework promotes communication between all organizations and individuals involved in an environmental project.

When critical environmental decisions need to be made (e.g., final decision-making or compliance with a standard), the project team should follow a formal systematic planning process such as the data quality objectives (DQO) process described in the *Guidance for the Data Quality Objectives Process* (EPA QA/G-4), August 2000, EPA/600/R-96/055. The formal DQO process as described in EPA QA/G-4 requires statistical expertise to define the amount of error acceptable when making an environmental decision and includes the following seven steps:

- Step 1. State the problem
- Step 2. Identify the decision
- Step 3. Identify the inputs to the decision
- Step 4. Define the study boundaries
- Step 5. Develop a decision rule
- Step 6. Specify tolerable limits on decision error
- Step 7. Optimize the design

Graded Approach

For data collection activities that are either exploratory or small in nature, or where specific decisions cannot be identified, the formal DQO process is not necessary. For these projects, the project team should use an abbreviated systematic planning process (e.g., Steps 1-4) to help identify the PQOs and action limits, and to select appropriate sampling, analytical, and assessment activities.

Estimating Measurement Error

This Manual requires that error be addressed at several key points in the QAPP. See Project Quality Objectives and Measurement Performance Criteria (Section 2.6), Field Documentation Procedures (Section 3.1.2.6), Quality Control Samples (Section 3.4), QA Management Reports (Section 4.2), and Data Review (Section 5.2).

Estimation of the amount of error that will be acceptable to meet the goals of the project is essential for proper planning. Measurement error is influenced by imperfections in the measurement and analysis system. Sampling error is generally thought to contribute the majority of the measurement error associated with project data, where:

Measurement Error = Sampling Error + Analytical Error

Random and systematic measurement errors are introduced in the measurement process during physical sample collection, sample handling, sample preparation, sample analysis, data reduction, transmission, and storage.

Once data have been generated, calculating the impact of the measurement error is a significant part of the data usability assessment. Measurement error can and does often lead to decision errors. Therefore, it is essential to reduce total project error to a minimum. This is done during planning by choosing an appropriate sample design and measurement system that will reduce the possibility of making a decision error.

Potentially relevant guidance documents have been added to the reference section.

Statistical analysis is beyond the scope of many projects; therefore, whether formal DQOs should be developed using the process described in EPA QA/G-4 will depend on the critical nature of the environmental decisions to be made as determined by the project team.

PQOs developed using a systematic planning process are presented as qualitative and quantitative statements that answer questions such as the following:

- Who will use the data?
- What will the data be used for? Simple, clear statements, such as the following should be used to describe anticipated data uses:
  - "These data will be used to determine if there is a potential current risk to human health during recreational use in the top foot of soil from contaminants exceeding specified action levels."
  - "These data will be used to determine the location of the leading edge of the contaminated plume, as measured by concentrations of ½ the action level at a ____% confidence interval."
  - "These data will be used to identify the presence or absence of DNAPL that may be a continuing source of contamination in groundwater."

> **Note:** The following are poor examples of PQOs because they are too vague and do not truly address the purpose of the data:
>
> - "These data will be used to determine the nature and extent of contamination."
> - "These data will be used to determine regulatory compliance with CERCLA statutes."
> - "These data will be used to assess the quality of the data generated by potentially responsible parties (PRPs)."

- What type of data are needed?
  - Target analytes and analytical groups
  - Field screening, on-site analytical, and/or off-site laboratory techniques
  - Type of sampling techniques (e.g., low-flow sampling)
- How "good" do the data need to be in order to support the environmental decision?
  - The quality of the data is determined by establishing criteria for performance measures, including precision, accuracy/bias, sensitivity (quantitation limits), data comparability, representativeness, and completeness.
- How much data are needed?
  - The number of samples needed for each analytical group, matrix, and concentration level.
- Where, when, and how should the data be collected or generated?
- Who will collect or generate the data?
- How will the data be reported?
- How will the data be managed and archived?

Site-specific PQOs identified at the scoping sessions should be documented in the QAPP using Worksheet #11 or a similar format.

2.6.2 Measurement Performance Criteria

Once the project team has defined the environmental decisions and identified the PQOs, the data users and QA personnel can determine the measurement performance criteria that should be satisfied in order to support defensible decisions.

Measurement performance criteria should be determined for each matrix, analytical group, concentration level, and analyte, if applicable. The criteria should relate to the parameters of precision, accuracy/bias, representativeness, comparability, sensitivity (quantitation limits), and completeness. The parameters indicate the qualitative and quantitative degree of quality associated with measurement data and, hence, are referred to as data quality indicators (DQIs).[3]

The QAPP should document the performance criteria for both the project-specific sampling and the analytical measurement systems that will be used to judge whether the project objectives have been met. For example, to determine whether the monitoring wells were installed correctly and will yield representative samples, the project team should identify appropriate performance criteria (e.g., during purging prior to sample collection, the monitoring wells must recover within ____ minutes in order to obtain an acceptable sample).

After measurement performance criteria have been established, the data generators and QA personnel should select sampling and analytical procedures and methods that have QC acceptance limits that support the achievement of established performance criteria.

> **Note:** The determination of the analytical data validation criteria should be concurrent with the development of measurement performance criteria and the selection of sampling and analytical procedures and methods. To ensure that only data meeting project-required measurement performance criteria are used in decision-making~~.~~, data users and QA personnel should select data validation criteria that support both the established project-specific measurement performance criteria and the analytical procedure and method QC acceptance limits (see Section 5.0).

Figure 14 (QAPP Worksheet #12) provides an example of the Measurement Performance Criteria table. This table should be completed for each matrix (soil, groundwater, sediment), analytical group, and concentration level. The analytical group can be described by common compound

[3]Data quality indicators should not be confused with the overall project quality objectives that are developed using the formal data quality objective process.

Matrix	*Ground Water*
Analytical Group[1]	*VOA*
Concentration Level	*Low*

Sampling Procedure[2]	Analytical Method/SOP[3]	Data Quality Indicators (DQIs)	Measurement Performance Criteria	QC Sample and/or Activity Used to Assess Measurement Performance	QC Sample Assesses Error for Sampling (S), Analytical (A) or both (S+A)
S-1	*L-1*	*Precision-Overall*	*RPD ≤ 30% when VOA detects for both field duplicate samples ≥ QL. RPD ≤ 40% when gaseous VOA detects for both field duplicate samples are ≥ QL.*	*Field Duplicates*	*S+A*
		Precision-Lab	*RPD ≤ 20% when VOC detects for both laboratory duplicate samples ≥ QL. RPD ≤ 30% when gaseous VOC detects for both laboratory duplicate samples are ≥ QL.*	*Laboratory Duplicates*	*A*
		Accuracy/Bias	*± 20% VOAs except volatile gases ± 40%*	*Surrogate Spikes*	*A*
		Accuracy/Bias	*No false negatives, no false positives, quantitation within warning limits (± 20)*	*Single-Blind PT*	*A*
		Accuracy/Bias Contamination	*No target compounds ≥ QL*	*Equipment Blanks, Field Blanks, Method Blanks & Instrument Blanks*	*S+A*
		Sensitivity	*± 40% at QL*	*Laboratory Fortified Blank at QL*	*A*

[1]If information varies within an analytical group, separate by individual analyte.
[2]Reference number from QAPP Worksheet #21 (see Section 3.1.2).
[3]Reference number from QAPP Worksheet #23 (see Section 3.2).

Figure 14. Example Measurement Performance Criteria (QAPP Worksheet #12)

groupings such as metals or semivolatile organic compounds. The concentration level may be a qualitative description (i.e., low, medium, high) as long as the terms are used consistently, are defined and agreed to by the project team.

A discussion of the DQIs for which measurement performance criteria should be developed follows.

2.6.2.1 Precision

Precision is the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision is usually expressed as standard deviation, variance, percent difference, or range, in either absolute or relative terms. *Precision data* indicate how consistent and reproducible the field sampling or analytical procedures have been.

The project team should determine and document the following:

- Quantitative measurement performance criteria for acceptable sampling and analytical precision for each matrix, analytical group, and concentration level.
- Analyte-specific measurement performance criteria, if applicable.
- QA/QC activities, or QC samples, that should be performed or analyzed to measure precision for each matrix, analytical group, and concentration level.

Overall project precision is measured by collecting data from co-located field duplicate (or replicate) samples. Precision specific to the laboratory is measured by analyzing laboratory duplicate (or replicate) samples. Comparing overall project precision and laboratory precision will help to identify sources of imprecision if a problem exists.

If only two separate samples are collected from adjacent locations and analyzed, these samples are referred to as *co-located field duplicates*. If two representative portions taken from a single sample are analyzed by the same laboratory, these are referred to as *subsample field duplicates*. If two aliquots of the same sample are prepared and analyzed by a laboratory, these samples are referred to as *laboratory duplicates*. If two aliquots of the same prepared sample are analyzed in duplicate, these samples are referred to as *analytical duplicates*. Duplicate precision is evaluated by calculating a relative percent difference (RPD) using the following equation (the smaller the RPD, the greater the precision):

$$RPD = \frac{|x_1 - x_2|}{(x_1 + x_2)/2} \times 100\%$$

where:

x_1 = original sample concentration
x_2 = duplicate sample concentration

If more than two duplicate samples are collected from adjacent locations and analyzed, these samples are referred to as *co-located field replicates*. If more than two representative portions are taken from a single sample and analyzed by the same laboratory, these samples are referred to as *subsample field replicates*. If two or more aliquots of the same sample are prepared and analyzed by a laboratory, these samples are referred to as *laboratory replicates*. If more than two aliquots of the same prepared sample are analyzed in replicate, these samples are referred to as *analytical replicates*. Replicate precision is evaluated by calculating the relative standard deviation (RSD), also referred to as the coefficient of variation, of the samples using the following equation (the smaller the RSD, the greater the precision):

$$\%RSD = \frac{Standard\ Deviation}{Mean} \times 100\%$$

where:

$$SD = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}}$$

x_i = each individual value used for calculating the mean
$\bar{x}$ = the mean of n values
n = the total number of values

Several software programs are available that will perform these calculations (RPD, RSD, SD). The type of software program used should be documented in the QAPP.

2.6.2.2 Accuracy/Bias

Accuracy is the degree of agreement between an observed value (sample result) and an accepted reference value; *bias* describes the systematic or persistent distortion associated with a measurement process. The terms *accuracy* and *bias* are used interchangeably in this document.

The project team should determine and document the following:

- Quantitative measurement performance criteria for acceptable accuracy/bias for each matrix, analytical group, and concentration level.
- Analyte-specific measurement performance criteria, if applicable.

- QA/QC activities, or QC samples, that should be performed or analyzed to measure accuracy/bias for each matrix, analytical group, and concentration level.

Analyte accuracy/bias can be evaluated using different types of QC samples. For example, a standard reference material or a laboratory control sample (LCS) that contains a known concentration of analyte(s) spiked into contaminant-free water or other blank matrix provides information about how accurately the laboratory (analysts, equipment, reagents, etc.) can analyze for a specific analyte(s) using a selected method. Single-blind and double-blind proficiency testing (PT) samples also provide information on how accurately the laboratory can analyze for a specific analyte using a selected method. The cumulative laboratory and method accuracy/bias is calculated as a percentage using the following equation:

$$Accuracy/Bias = \frac{Measured\ Value}{True\ Value} \times 100\%$$

Because environmental samples contain interferences (i.e., other compounds that may interfere with the analysis of a specific analyte), the accuracy/bias for a specific analyte should be evaluated in relation to the sample matrix. This is done by analyzing matrix spike samples. A known concentration of the analyte is added to an aliquot of the sample. The difference between the concentration of the analyte in the unspiked sample and the concentration of the analyte in the spiked sample should be equal to the concentration of the analyte that was spiked into the sample. The spike recovery is calculated as a percentage using the following equation:

$$\%Recovery = \frac{Spiked\ Sample\ Conc. - Unspiked\ Sample\ Conc.}{Spiked\ Conc.\ Added} \times 100\%$$

Frequently, matrix spike samples are prepared and analyzed in duplicate, especially for organic analyses, to provide sufficient precision and accuracy data to evaluate achievement of project quality objectives.

Note: In general, published methods provide precision and accuracy/bias statements that are supported by data generated during method validation studies. Additionally, laboratories should track and maintain records of precision and accuracy/bias trends for their QC samples (such as laboratory duplicates/replicates, standard reference materials, LCSs, and matrix spike analyses) and include acceptable precision and accuracy/bias ranges in their analytical SOPs. Published QC data and familiarity with routine method performance will allow project planners to choose project-required measurement performance criteria that are technically feasible.

2.6.2.3 Sensitivity and Quantitation Limits

Sensitivity is the ability of the method or instrument to detect the target analytes at the level of interest. The *quantitation limit* (QL) is the minimum concentration of an analyte that can be routinely identified and quantified above the method detection limit (MDL) by a laboratory. Sensitivity can be measured by calculating the percent recovery of the analytes at the QL. The project team should document the project-required QLs for each matrix, analytical group, concentration level, and analyte.

The project team should determine and document the following:

- Quantitative measurement performance criteria for acceptable sensitivity to ensure that QLs can be routinely achieved for each matrix, analytical group, and concentration level.
- Analyte-specific measurement performance criteria, if applicable.
- QA/QC activities, or QC samples, that will be performed or analyzed to measure sensitivity.

The following issues should be considered when selecting project-specific QLs:

- A laboratory MDL is a statistically derived detection limit that represents a 99 percent confidence level that the reported signal is different from a blank sample. The MDL is lower than the concentration at which the laboratory can quantitatively report. Laboratories determine their "best case" sensitivity for analytical methods by performing MDL studies.
- Laboratory achievable QLs should be at least 3 times the achievable laboratory MDL and ideally 10 times the achievable laboratory MDL.
- In the UFP-QAPP, the reporting limit is the *quantitation limit* achievable by the laboratory. The reporting limit must be at or below the project quantitation limit.
- Frequently, QLs for specific samples are adjusted for dilutions, changes to sample volume/size and extract/digestate volumes, percentage of solids, and cleanup procedures. These QLs are referred to as *sample quantitation limits* (SQLs).
- The *action limit* (AL) for a target analyte is the numerical value the decision-maker uses as the basis for choosing one of the alternate actions. It may be a regulatory threshold such as maximum contaminant levels (MCLs), a risk-based concentration level, a reference-based standard, or a technological limitation.
- SQLs must be *less than* the action limits for project quality objectives to be definitively met. Sample results that are reported to SQLs that are higher than the action limits cannot be used to determine whether the action limit has been exceeded. Thus, environmental decision-making may be adversely affected by the failure to meet QLs.
- Because of uncertainty at the quantitation limit, project QLs should be no greater than one-third of the action limit and ideally one-tenth of the action limit.

Method and instrument sensitivity may be evaluated by preparing and analyzing a laboratory fortified blank (LFB). An LFB is a blank matrix that is spiked at the QL with the target analytes. Calibration curves should always include a standard concentration at the QL to ensure sensitivity. Low-point calibration standards should produce a signal at least 10 times the background level and should be part of a linear calibration curve.

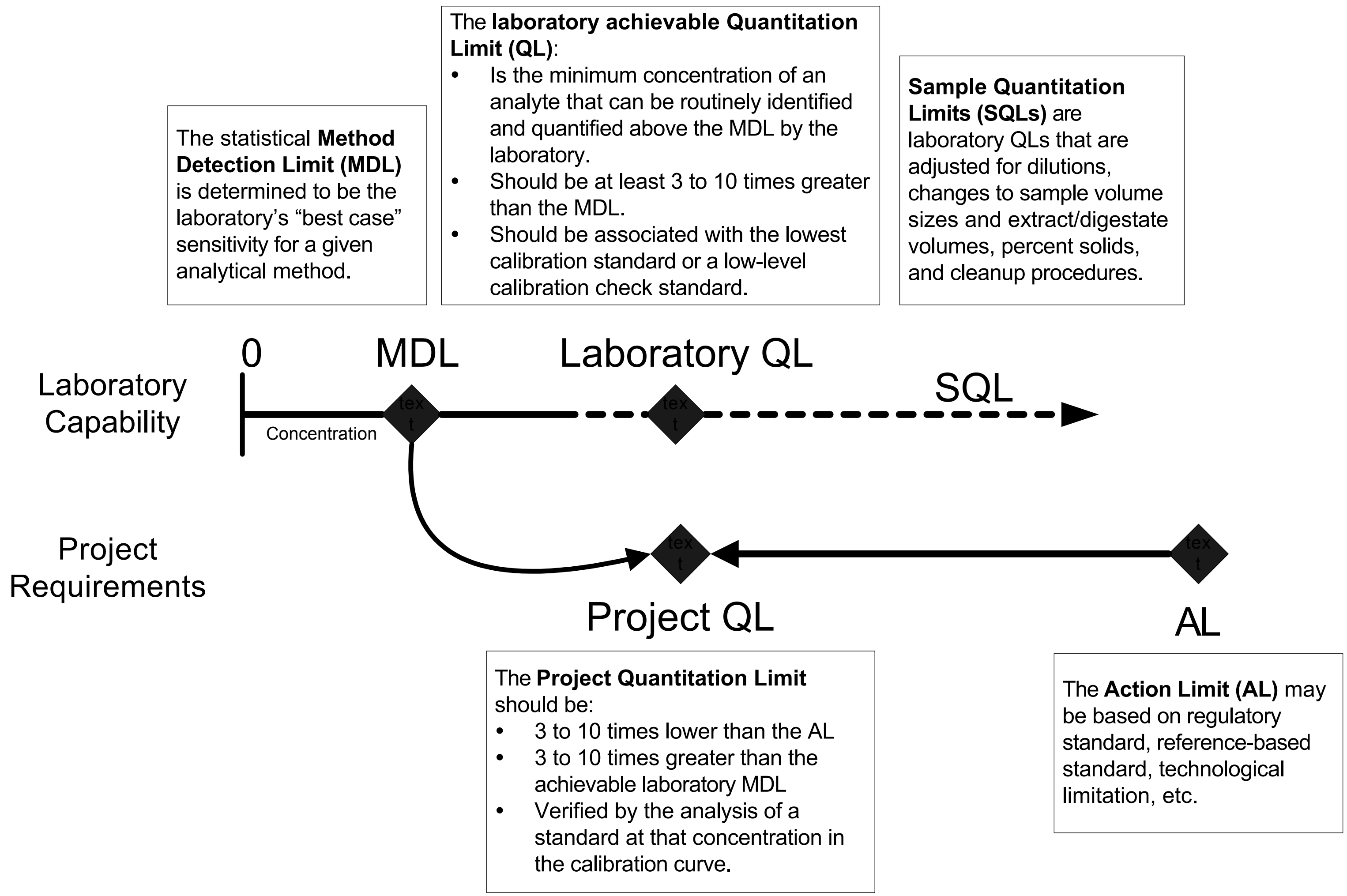
The QAPP should differentiate between action limits and project-required QLs. The QAPP should also differentiate between MDLs and QLs that are documented in a published analytical method and MDLs and QLs that an individual laboratory can routinely achieve. Figure 15 shows the relationships between MDLs, laboratory achievable QLs, SQLs, project-specific QLs, and action limits.

2.6.2.4 Representativeness

Representativeness is a qualitative term that describes the extent to which a sampling design adequately reflects the environmental conditions of a site. It takes into consideration the magnitude of the site area represented by one sample and indicates the feasibility and reasonableness of that design rationale. Representativeness also reflects the ability of the sample team to collect samples and the ability of the laboratory personnel to analyze those samples so that the generated data accurately and precisely reflect site conditions. In other words, a discrete sample that is collected and then subsampled by the laboratory is representative when its measured contaminant concentration equates to the contaminant concentration of some predefined vertical and horizontal spatial area at the site. Sample homogeneity, and sampling and subsampling variability, should be considered when developing criteria for representativeness. The use of statistical sampling designs and standardized SOPs for sample collection and analysis help to ensure that samples are representative of site conditions.

The project team should determine and document the following:

- Qualitative measurement performance criteria for acceptable representativeness for each matrix, analytical group, and concentration level.
- Analyte-specific measurement performance criteria, if applicable.
- QA/QC activities, or QC samples, that should be performed or analyzed to measure representativeness for each matrix, analytical group, and concentration level.


The statistical **Method Detection Limit (MDL)** is determined to be the laboratory's "best case" sensitivity for a given analytical method.
The **laboratory achievable Quantitation Limit (QL)**:
• Is the minimum concentration of an analyte that can be routinely identified and quantified above the MDL by the laboratory.
• Should be at least 3 to 10 times greater than the MDL.
• Should be associated with the lowest calibration standard or a low-level calibration check standard.
Sample Quantitation Limits (SQLs) are laboratory QLs that are adjusted for dilutions, changes to sample volume sizes and extract/digestate volumes, percent solids, and cleanup procedures.
Laboratory Capability
0
MDL
Laboratory QL
SQL
Concentration
Project Requirements
Project QL
AL
The **Project Quantitation Limit** should be:
• 3 to 10 times lower than the AL
• 3 to 10 times greater than the achievable laboratory MDL
• Verified by the analysis of a standard at that concentration in the calibration curve.
The **Action Limit (AL)** may be based on regulatory standard, reference-based standard, technological limitation, etc.

2.6.2.5 Comparability

Comparability is the degree to which different methods or data agree or can be represented as similar. It describes the confidence that two data sets can contribute to a common analysis and interpolation.

The project team should determine and document the following:

- Quantitative performance criteria for acceptable data comparability for each matrix, analytical group, and concentration level.
- Analyte-specific measurement performance criteria, if applicable.
- QA/QC activities, or QC samples, that should be performed or analyzed to measure data comparability for each matrix, analytical group, and concentration level.

The QAPP should address issues such as consistency in sampling and analytical procedures within and between data sets. For example, to ensure data comparability for repeated monitoring well sampling, SOPs should require that well casings be notched or permanently marked so that the water level measurement is taken from the same spot for each sampling event.

2.6.2.5.1 *Split Sampling Data Comparability*

Split samples are two or more representative portions taken from a sample in the field or laboratory and analyzed by at least two different laboratories to assess precision, variability, and data comparability between laboratories and/or methods.

Whenever split sampling and analysis are performed (e.g., multiple data generators on the same project or as part of EPA oversight of the lead organization and its contractors and subcontractors), comparability criteria must be established and documented in the QAPP or the oversight QAPP prior to data collection. Comparability criteria should be determined for each matrix, analytical group (and analyte, if applicable), and concentration level. Split sampling comparability criteria must specify the following:

1. Acceptable relative percent difference (RPD) for individual analyte comparisons (for combinations of nondetects, detects close to the QLs, and detects sufficiently greater than the QLs).
2. Acceptable percentage of analytes (per matrix, analytical group, and concentration level) with acceptable RPDs.
3. Acceptable magnitude and direction of bias for comparisons performed in 1 and 2 above.
4. Acceptable overall comparability criteria for all data generated for use in the project.
5. Corrective action and process for reconciliation of any differences, if overall comparability criteria are not met.

PT samples should be used to identify the magnitude and direction of bias for each data generator. The results should be compared with 3, above, and with the project-specific measurement performance criteria so that data usability decisions can be made.

Whenever split sampling is performed, a comparability flow diagram must be included in the QAPP (see Figure 16) . The equation used to calculate RPD between split sample results generated by two different laboratories is at the bottom of Figure 16. This equation uses absolute values since it assumes that values generated by equivalent methods used by multiple entities are equally accurate.

2.6.2.5.2 *Screening Versus Definitive Data Comparability*

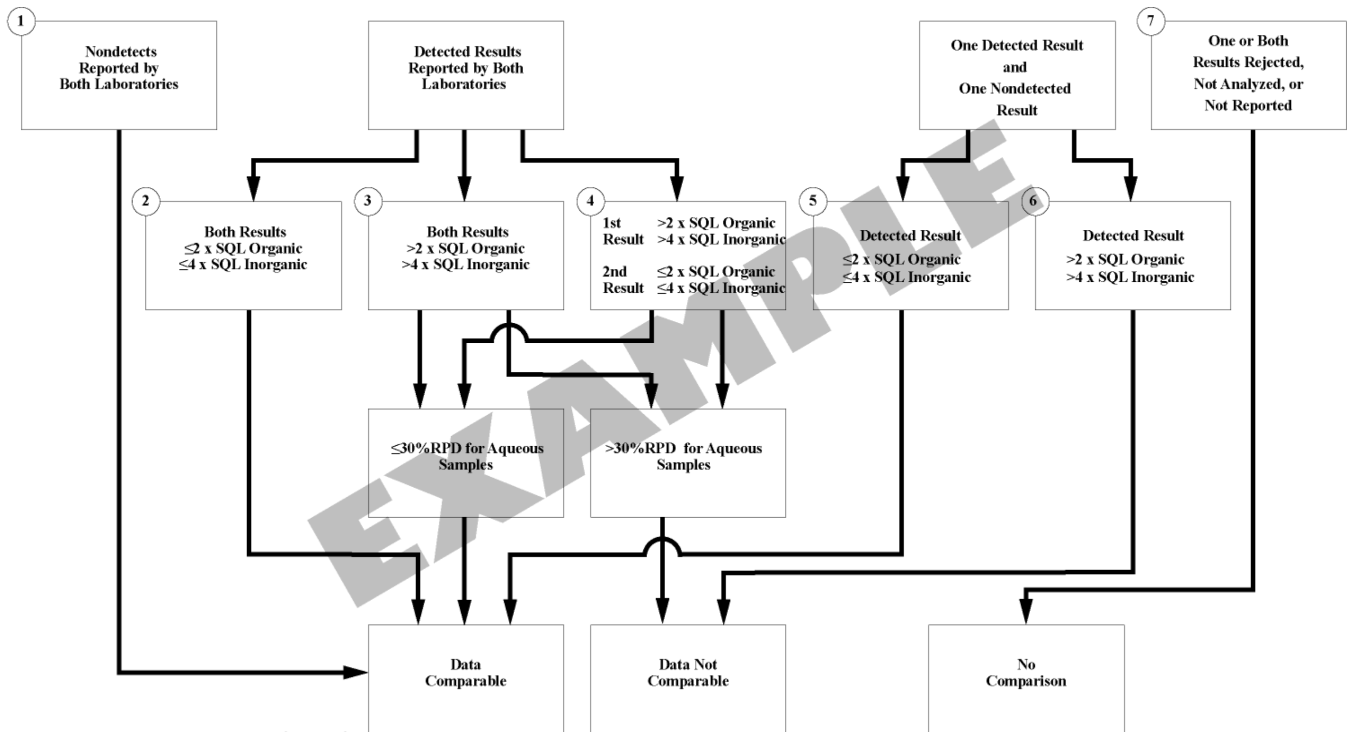
Whenever definitive analysis is performed to confirm screening results, comparability criteria must be established and documented in the QAPP prior to data collection. Comparability criteria must be determined for each matrix, analytical group (and analyte, if applicable), and concentration level.

The most important factor for determining whether screening data will meet the PQOs and be usable for project decision-making is the comparability of screening data and split sample confirmation data generated using definitive analytical methods. Because data comparability decisions are based on a limited number of samples analyzed by the definitive analytical methods, the methods that are used to confirm screening results must be scientifically valid, well-documented methods that have routinely been accepted by regulators.

> **Screening Data Versus Definitive Data**
>
> **Screening data** are analytical data that are of sufficient quality to support an intermediate or preliminary decision but must eventually be supported by definitive data before a project is complete.
>
> **Definitive data** are analytical data that are suitable for final decision-making.

When developing comparability acceptance criteria for screening and definitive data, the following issues should be considered:

- Are the screening and definitive methods based on the same analytical principles? If the screening and definitive methods measure target analytes using different principles, then a one-to-one correlation should not be assumed.
- Do the screening and definitive methods analyze for the same list of target analytes? If not, then a one-to-one correlation should not be assumed.
- Do the screening and definitive methods report to the same QL? If not, how will data that are reported below the QL of either method be handled? Also, are the QLs for the screening and definitive methods significantly less than the action limits?
- Do the screening and definitive methods have the same extraction efficiencies, use the same sample volumes, and perform similar sample pretreatment and sample cleanup? These differences may also account for correlations that are not one-to-one.



Notes:

$$\text{RPD (relative percent difference)} = \frac{|C_1 - C_2|}{\left(\frac{C_1 + C_2}{2}\right)} \times 100\%$$

SQL = Sample Quantitation Limit is the quantitation limit adjusted for any necessary sample dilutions, sample volume deviations, or extract/digestate volume deviations.
The numbers shown in this figure are for illustration purposes only. Site-specific criteria must be developed for each project by the project team.

99-138.06

Figure 16. Example Data Comparison Flow Diagram and Criteria for Results from Two Different Laboratories Analyzing Individual Aqueous Split Samples (generated using equivalent analytical methods and achieving equivalent QLs)

- How will percentage of moisture be accounted for in both screening and definitive samples?
- Are the calibration procedures the same for the screening and definitive methods? That is, will standard calibration curves or single-point calibrations be generated?

Screening versus definitive comparability criteria must specify the following:

1. Acceptable percent differences for individual analyte comparisons (for combinations of nondetects, detects close to the QLs, and detects sufficiently greater than the QLs).
2. Acceptable percentage of analytes (per matrix, analytical group, and concentration level) with acceptable percent differences.
3. The acceptable magnitude and direction of bias for comparisons performed in 1 and 2 above.
4. Acceptable overall comparability criteria for all data generated for use in the project.

Whenever screening versus definitive split sampling is performed, a comparability flow diagram must be included in the QAPP. Multiple flow diagrams may be needed to address QL differences between screening and definitive methods.

Figure 17, Example Comparability Determination, illustrates two approaches that can be used for determining the comparability of screening and definitive data. One approach involves the generation and application of predesign correlation factors to adjust screening sample results prior to performing data comparability calculations. Correlation factor adjustment of screening sample results can be critical when a one-to-one correlation does not exist for data generated with the screening and definitive methods (depending on differences in method selectivity, sensitivity, precision, and accuracy, as well as on the relationship of the laboratory achievable QLs to the action limits). The equation used to define percent difference when comparing screening and definitive results is included at the bottom of Figure 17. The equation assumes that values generated by the definitive method are more accurate than those generated by the screening method. While this may not always be true, the equation serves to standardize reporting conventions and to promote data comparability. Note that this equation retains the sign of the difference, thus absolute values are *not* used.

The other approach for determining the comparability of screening and definitive data does not use correlation factor adjustment of screening sample results prior to performing data comparability calculations. Comparability calculations that are performed with screening and definitive data for which correlation factors have not been generated or applied may result in project-specific comparability criteria being exceeded (especially if those criteria are tight).

Both approaches require that data comparability acceptance criteria be developed and documented in an approved project QAPP prior to initiation of field sampling activities.

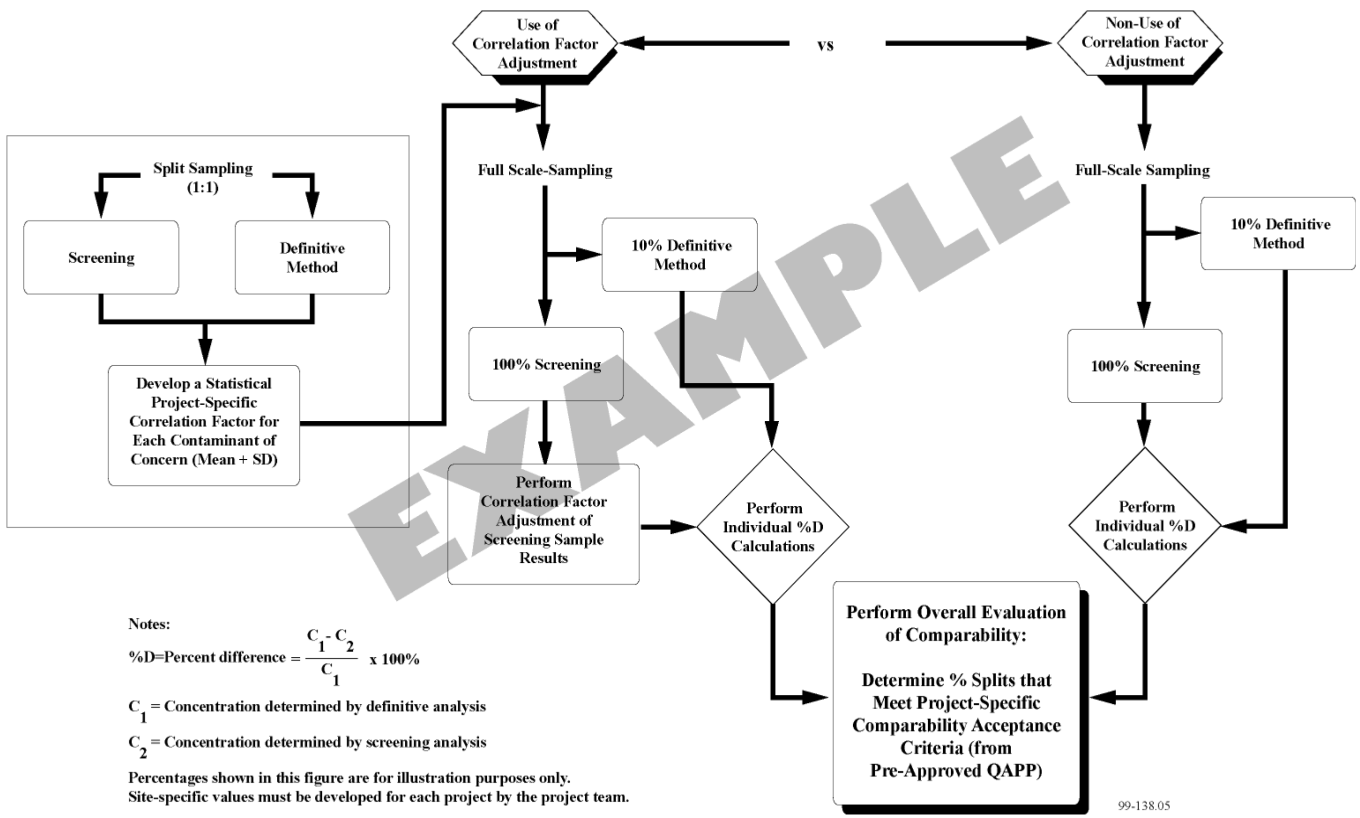


Figure 17. Example Comparability Determination

2.6.2.6 Completeness

Completeness is a measure of the amount of valid data collected using a measurement system. It is expressed as a percentage of the number of measurements that are specified in the QAPP.

The QAPP should address how completeness will be determined by specifying the following:

- Performance criteria for acceptable completeness for each matrix, analytical group, and concentration level.
- Analyte-specific measurement performance criteria, if applicable.
- QA/QC activities that should be performed to measure completeness.

Separate values should be provided for the whole data set, not just for the critical data subset. Since lack of data completeness may require resampling and additional costs, the QAPP should discuss how sufficient data will be guaranteed for critical sample locations.

2.7 Secondary Data Evaluation

Previous sections discussed project quality objectives, measurement performance criteria and associated data quality indicators. In determining what data must be collected, the first step should be evaluation of existing data to determine if they meet project needs. Secondary data may include data generated for or by external, independent parties which are then transmitted to the current user. Secondary data may also include data collected in other investigations designed to answer different questions than those posed in the current investigation. Using data and information that are not generated for the same quality objectives as the current investigation may result in erroneous decisions; therefore, it is essential to identify use limitations for secondary data. Figure 18 outlines the process used to evaluate secondary data. All items listed under "Information Needed" may not be available; however, the project team should evaluate whatever information is available.

The QAPP should identify sources of previously collected data and other information that will be used to make project decisions. Sources of secondary data and information include, but are not limited to:

- Historical data (e.g., from an organization's or facility's corporate records and/or Federal, State, or local records pertaining to previous monitoring events, site assessments, or investigations). Historical data may be used to describe the site history and define the environmental problem (see Section 2.5.2 of this Manual).
- Background information and data from an organization's or facility's corporate records and/or Federal, State, or local records pertaining to site-specific industrial processes, process by-

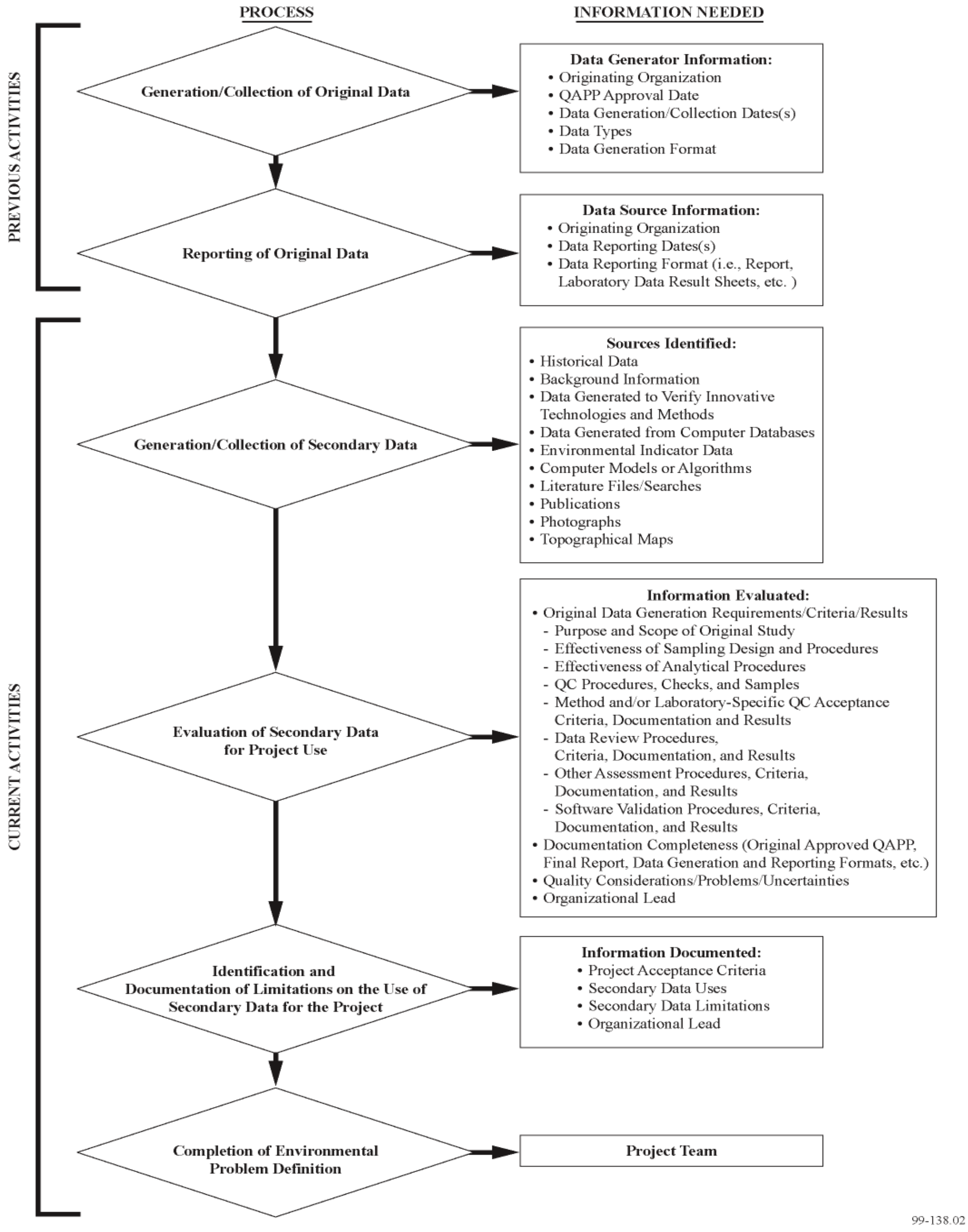


Figure 18. Secondary Data Evaluation Process

products, past and current chemical uses, raw material and finished product testing, waste testing and disposal practices, and potential chemical breakdown products.
- Data generated to verify innovative technologies and methods.
- Data generated from computer databases (such as manufacturers' process and product information, or waste management or effluent information).
- Environmental data obtained from Federal, State, or local records.
- Computer models or algorithms.
- Literature files and searches.
- Publications.
- Photographs.
- Topographical maps.

Note: To ensure that correct environmental decisions are made, the same care should be taken when using secondary data as is taken when generating new data.

Note: The information may be presented in tabular format, however, since the table will not be able to present all required information regarding secondary data, it will be necessary to provide additional information in the text.

All secondary data and information that will be used for the project, their originating sources, their planned uses, and any limitations on their use should be provided in the QAPP. Figure 19 (QAPP Worksheet #13) provides an example of the Secondary Data Criteria and Limitations table.

Secondary Data	Data Source (Originating Organization, Report Title, and Date)	Data Generator(s) (Originating Org., Data Types, Data Generation/Collection Dates)	How Data Will Be Used	Limitations on Data Use
Soil Gas Data	*BioWatch Consulting, LTD: "Titanic Shipyard Investigation Report, " 11/20/95*	*BioWatch Consulting, LTD: VOC Soil Gas Data, Sample Collection Dates: 10/19-23/95*	*To assess the potential sources of contaminated soil and resultant groundwater migration*	*1. Unvalidated data used to generate report* *2. Insufficient data points to fully characterize on-site contamination and off-site migration*
Municipality Drinking Water Data	*XYZ Municipality: Quarterly Drinking Water Check Report, 6/95 - 6/96*	*Smith Laboratories, Inc.: VOC Drinking Water Data, Sample Collection Dates: 6/12/95, 9/15/95, 12/10/95, 3/6/96, 6/12/96*	*To assess existing groundwater contamination*	*1. Unvalidated data used to generate report* *2. Limited number of wells exist to sample*

Figure 19. Example Secondary Data Criteria and Limitations (QAPP Worksheet #13)

Once the secondary data sources have been identified, the project team should evaluate and discuss how well the quality of the data meets the Project Quality Objectives and associated MPC, as well as the completeness of its documentation. The QAPP should identify the following:

- Generator(s) of the data.
- Dates the data were generated, collected, and reported.
- Sources from which the data were obtained.
- Procedures originally used to generate and collect the data (including sampling, analytical, and assessment procedures).
- All QC procedures, checks, and samples that were analyzed with the data set, if known.
- Method and/or laboratory-specific QC acceptance criteria used for data generation and whether or not data were reviewed.
- If data were reviewed, the criteria and procedures used, the documentation provided, and the results obtained from previous data review activities (see Section 5.0 for a complete discussion of data review).

Additional items to address in the text related to the quality of the secondary data include the following:

- If the data were generated under an approved QAPP or other sampling document, reference the document by title, date, originating organization, and approving organization.
- Evaluate the purpose and scope of previous studies and compare with current study objectives.
- Evaluate similarities and differences of the measurement performance criteria and data quality indicators.
- Evaluate the design and implementation of previous studies by examining the following:
  - Whether the study was conducted properly
  - Whether control responses were within acceptable limits
  - Whether standard sampling and analytical methods and standard QA/QC protocols were available and followed
- Include a brief description of the sampling procedures for each matrix type (e.g., grab/grid for surficial soils) and analytical procedures for each matrix type (e.g., SW-846 Method 3550/8270 for surficial soils).
- If performance or system audits or split sampling activities were performed, provide a synopsis of the results of those audits or activities.
- If data were reviewed, reference the data review procedure by title, date, and originating organization.
- If data were obtained from a computer model or algorithm, provide a brief description of the validation of that computer software.
- If data were obtained from a database, provide a brief discussion on the integrity and accuracy of the database information.

- Discuss the adequacy of the original QA documentation under which secondary data were generated. For example, if sufficient raw analytical data are not available to verify that an instrument was calibrated accurately, then the secondary data may not be usable for their intended purpose.
- Relate the secondary data back to the PQOs and MPCs.

The QAPP should discuss all possible limitations on the use of secondary data for the project based on the uncertainty surrounding their quality, including the following:

- The nature and magnitude of the uncertainty. For example, discuss the impact of using unreviewed historical monitoring data to answer project questions and support project decisions. Unreviewed data may be scientifically inaccurate or may not meet the objectives of the user.
- The impact of using secondary data with known analytical or sampling inaccuracy or bias, or known imprecision. For example, document the sampling and analytical methods used to collect and analyze soil VOA samples, and discuss possible low bias in sample results.
- The acceptance criteria used to determine whether the secondary data and information are usable for the project. For example, if secondary drinking water data will be used to answer project questions, the QAPP should state that only data generated by EPA/State-certified or NELAP-accredited Safe Drinking Water Act laboratories will be used for the project.
- The comparability criteria for secondary data (e.g., historical routine monitoring data) and the data generated for the current project.

2.8 Project Overview and Schedule

The QAPP should provide a general overview of the activities that will be performed, and how and when they will be performed, based on background information and data, preplanning site visits, and scoping sessions. Specific details for the individual project activities will be provided in later sections of the QAPP.

2.8.1 Project Overview (Outcome of Project Scoping Activities)

Through project planning, the project team should agree on the purpose of the project, the environmental questions that are being asked, and the environmental decisions that must be made. The project team should establish the PQOs (i.e., specify the type, quantity, and quality of data needed to ensure that project data can be used for the intended purpose) to answer specific environmental questions, support environmental decisions, and determine technical activities that will be conducted. Figure 20 (QAPP Worksheet #14) provides an example of the Summary of Project Tasks table.

Sampling Tasks: *10 groundwater (GW) samples; 2 existing wells; and 8 newly installed wells*
24 soil boring (SB) samples; 3 from each of 8 borings-during well installation
100-120 surface soil (SS) samples; 50 collected 0-1' depths on grid; 50 random; 20 contingency sample
6 surface waters (SW); 2 from Ruby Brook; 4 from water in depressions
6 sediment (SED) samples from Ruby Brook; 6 leachate samples on steep hill east of site

Analysis Tasks: *GW - VOC 5030B/8260B, SVOC 3520C/8270C, Pest 3510C/8081A, PCB 3510C/8082, Metals 3051/6010B, Mercury 7470A*
SW - VOC 5030B/8260B, SVOC 3520C/8270C, Pest 3510C/8081A, PCB 3510C/8082, Metals 3051/6010B, Mercury 7470A
SS - VOC 5035/8260B, SVOC 3550C/8270C, Pest 3541/8081A, PCB 3541/8082, Metals 3051/6010B, Mercury 7471A
SB - VOC 5035/8260B, SVOC 3550C/8270C, Pest 3541/8081A, PCB 3541/8082, Metals 3051/6010B, Mercury 7471A
SED - SVOC 3550C/8270C, Pest 3550B/8081A, PCB 3541/8082, Metals 3051/6010B, Mercury 7471A
Leachate - SVOC 3520C/8270C, Pest 3510C/8081A, PCB 3510C/8082, Metals 3051/6010B, Mercury 7470A

Quality Control Tasks: *All matrices will have the following QC samples analyzed: duplicates, matrix spikes, matrix spike duplicates, VOA trip blanks, equipment blanks, bottle blanks, and PE samples.*
All analytical methods will perform: initial calibrations, continuing calibrations, tuning, reagent blanks, surrogates, replicates, laboratory control spikes, and all other applicable QC defined in the method.

Secondary Data: *Data for 1982-83 inspections, 1985 initial investigation, Fire Department records, waste manifests, and company records will be reviewed. All data will be evaluated for project use. Limitations to documentation will be noted. Data deemed as valuable will be added to database.*

Data Management Tasks: *Analytical data will be placed in a database after validation. The database will also compile field measurements. Secondary data deemed usable will be added to the database. All data will be assessed by the Case Team.*

Documentation and Records: *All samples collected will have locations GPS documented, records of each sample collected in notebooks, and all field measurements documented in notebooks. COCs, airbills, and sample logs will be collected for each sample.*

Data Packages: *All data packages will include: all elements listed in Table 6 of Compendium.*

Assessment/Audit Tasks: *Sampling SOPs reviewed; PRPs will be notified March 1, 15, 22, 27, 30 by phone and letter; Field Sample Collection and Documentation Audits: April 1, 15, 22, 27, and 30, 2000; no laboratory TSA.*

Data Review Tasks: *Each laboratory performing analyses of samples will verify that all data are complete for samples received. Data will be validated using Tier II, Region 1, EPA-New England Data Validation Functional Guidelines for Evaluating Environmental Analysis.*
All deliverables required. Validated data will be reviewed. Data usability will be assessed; MPC met? Sample & analytical error ? Spatial variability?
Measurement performance criteria set in QAPP checked. Were QL requirements met? Data limitations will be determined. Data compared to Project Objectives.
Corrective action initiated, data are placed in database, tables, charts, and graphs are generated. Data compared to historical data.

Figure 20. Example Summary of Project Tasks
(QAPP Worksheet #14)

The project team should also agree on what environmental characteristics of interest or target analytes/contaminants of concern (COCs) will be measured. The list of target analytes/COCs should be refined as much as possible using the information available and may increase or decrease as the project progresses.

Graded Approach

The identification of target analytes/contaminants of concern represents one of the greatest opportunities for focusing a project, thereby saving time and money. Whenever possible, the list of target analytes/COCs should include those most likely to be found on the site. In some cases (e.g., an old fire training pit where a wide range of analytes may have been burned), devising a short list early in the project is difficult. Some people mistakenly believe, however, that if you have identified one or two analytes from an analyte group with a long list of analytes (e.g., semivolatile compounds), you might as well analyze the whole list of SVOCs (more than 70 compounds). Using fewer analytes provides the potential for significantly improving the quality of the analysis (e.g., improvements in accuracy by optimizing the method for the specific chemical) as well as saving time and money.

The project team should determine the quality criteria that the data must meet to achieve the project objectives, and document those measurement performance criteria in the QAPP. Project-required QLs and action limits must be established prior to the selection of sampling and analytical methods. To compensate for potential analytical inaccuracy at the QL, project-required QLs should be at least 3 to 10 times less than the action limits, if achievable.

The QLs from individual methods and laboratories are evaluated relative to project-required action limits to determine their suitability to meet PQOs. If the published method QL exceeds the action limit for a target analyte/COC, that analytical method is unacceptable for the analysis of that analyte. However, if a laboratory has modified the published method to achieve QLs that are less than the action limits, and it has documented this modification in its laboratory SOP, that laboratory SOP might constitute an acceptable method. See Section 2.6.2.3 for additional guidance on QLs.

Figure 21 (QAPP Worksheet #15) shows an example Reference Limits and Evaluation table. Separate tables should be provided for each matrix, concentration level, and analytical group.

Note: Achievable MDLs and QLs are those that an individual laboratory can achieve when performing a specific analytical method. An individual laboratory may not always be able to achieve the MDLs and QLs that are in a published method. Therefore, even though a published analytical method may meet project requirements, a laboratory may not necessarily perform the analytical method satisfactorily. Laboratory-achievable MDLs and QLs must be documented in the laboratory's SOP for each analytical method used by the laboratory for the project.

Matrix: *Groundwater*
Analytical Group: *VOA*
Concentration Level: *Low*

Analyte	CAS Number	Project Action Limit (applicable units)	Project Quantitation Limit (applicable units)	Analytical Method Limits[1]		Achievable Laboratory Limits[2]	
				MDLs	Method QLs	MDLs	QLs
Benzene	*71-43-2*	*5 Fg/L*	*1 Fg/L*	*0.03*	*Not provided in method*	*0.1*	*0.5*
Trichoroethene	*79-01-6*	*5 Fg/L*	*1 Fg/L*	*0.02*	*Not provided in method*	*0.11*	*0.5*
Vinyl Chloride	*75-01-4*	*2 Fg/L*	*1 Fg/L*	*0.04*	*Not provided in method*	*0.11*	*0.5*
1,2-Dicholoroethane	*107-06-2*	*5 Fg/L*	*1 Fg/L*	*0.02*	*Not provided in method*	*0.11*	*0.5*
Carbon Tetrachloride	*56-23-5*	*5 Fg/L*	*1 Fg/L*	*0.08*	*Not provided in method*	*0.12*	*0.5*
1,2-Dichloropropane	*78-87-5*	*5 Fg/L*	*1 Fg/L*	*0.02*	*Not provided in method*	*0.11*	*0.5*
1,1,2-Trichloroethane	*79-00-5*	*5 Fg/L*	*1 Fg/L*	*0.03*	*Not provided in method*	*0.13*	*0.5*

[1]Analytical method MDLs and QLs are those documented in published methods.
[2]Achievable MDLs and QLs are limits that an individual laboratory can achieve when performing a specific analytical method.

Figure 21. Example Reference Limits and Evaluation (QAPP Worksheet #15)

If the laboratory and method cannot achieve the project QLs and action limits, one of the following options should be pursued:

Option 1 — Use a different laboratory.
Option 2 — Use an alternative analytical method or a modified method.
Option 3 — Accept a higher level of uncertainty for data falling between the MDL and QL.
Option 4 — Adjust the action limits to reflect the capability of available methods to detect the target analytes/COCs.

2.8.2 Project Schedule

The QAPP should include a schedule of the work to be performed using a timeline or tabular format (see Figure 22, QAPP Worksheet #16). The timeline must include the start and completion dates for all project activities, as well as the quality assurance assessments that will be performed during the course of the project. Sufficient time for document review and implementation of effective corrective actions should be scheduled.

In addition to the timeline, the procedure for notifying project participants concerning project schedule delays should be included in the QAPP. This description should include identification, by job function and organization name, the personnel responsible for providing and receiving such notification, and the personnel responsible for approving schedule delays.

Graded Approach

For projects that involve only routine monitoring, such as NPDES compliance monitoring, the schedule may include only the dates of the sampling and the date the results are due to the regulatory oversight authority.

		Dates (MM/DD/YY)			
Activities	**Organization**	**Anticipated Date(s) of Initiation**	**Anticipated Date of Completion**	**Deliverable**	**Deliverable Due Date**

Figure 22. Project Schedule/Timeline (QAPP Worksheet #16)

The QAPP should include a discussion of all project-related resource, political, and time constraints, along with seasonal sampling restrictions and considerations. All regulatory requirements and/or restrictions, and any other factors that will affect the project schedule, should be identified.

3.0 MEASUREMENT AND DATA ACQUISITION ELEMENTS

This QAPP element group covers how project data will be collected, measured, and documented. Proper implementation of these activities will help ensure that resulting data are scientifically sound, of known and documented quality, and suitable for their intended use.

This section of the Manual addresses quality control activities that will be performed during each phase of data collection and generation, from sampling to data reporting, evaluating QC acceptance limits, and the performance of corrective actions for nonconformances. It is important to remember that each phase of data collection and generation is interdependent and that, therefore, quality must be factored into all project activities or tasks. The final two QAPP element groups, Assessment/Oversight and Data Review, evaluate the activities or tasks described in this element group.

> **Graded Approach**
>
> To simplify QAPP preparation, written SOPs should be included as attachments to the QAPP whenever possible. If procedures are documented in a separate document, that document should be cross-referenced, as shown in the example in Table 2, and either attached for review and approval (if not already approved) or referenced with sufficient specificity that it can be easily found. Information in attachments to the QAPP can be provided in an electronic format (such as portable document format (PDF); on CD-ROM, DVD-R, or other storage media; or on a website).

All sampling and analysis procedures that will be used in the project must be documented in the QAPP or attached documents. Attachments must be provided with, or clearly referenced in, the QAPP to allow for review and approval. SOPs must provide a detailed step-by-step description of each procedure, in addition to acceptable limits of performance and required corrective actions, if applicable. Analytical methods and SOPs must specify appropriate QC checks and samples with explicit concentration and frequency requirements for preparation and analysis. When a single SOP has multiple options for a given procedure, which is common, the QAPP must identify the option that applies to the project. If routine SOPs are modified to meet PQOs, the modification(s) must be described in the QAPP along with an indication that a modification occurred. Appendix A contains examples of the types of SOPs that should be included in the QAPP, with additional detail on their content.

> **Writing and Formatting SOPs and Methods**
>
> EPA QA/G-6, *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents* (EPA/240/B-01/004, March 2001 or most recent revision) provides guidance for writing and formatting SOPs. The Environmental Monitoring Management Council Methods Format (www.epa.gov/ttn/emc/guidlnd/gd-045.pdf) provides guidance for writing and formatting analytical methods.

3.1 Sampling Tasks

The sampling sections of the QAPP include all components of the project-specific sampling system, including process design and rationale, procedures, and requirements.

The QAPP must contain sufficient documentation to assure the reviewer that representative samples from the appropriate matrix will be properly and consistently collected at the appropriate locations and that preventive and corrective action plans are in place prior to initiation of the sampling event.

Definition of Sample

Since the definition of *sample* is program-dependent, the term must be defined or the regulatory definition referenced in the QAPP to ensure the correct usage. For example, if a soil sample is defined in the field by mesh size, then this should be noted. If a laboratory then subsamples this field sample based on the criteria of mesh size, then those activities and definitions should also be documented.

3.1.1 Sampling Process Design and Rationale

The outcome of the project scoping activities, including project quality objectives, measurement performance criteria, and the acceptable level of uncertainty (see Section 2.8.1), should be used to identify appropriate sampling design(s). The QAPP should describe the project team's rationale for choosing the sampling process design methodology (e.g., grid system, biased statistical approach), and describe the sampling system (design) in terms of what matrices will be sampled, where the samples will be taken, the number of samples to be taken, and the sampling frequency (including seasonal considerations). Whether the QAPP applies to an initial site investigation, a large-scale remedial investigation/feasibility study (RI/FS), a long-term treatment monitoring program, or a volunteer monitoring program, the rationale for sampling specific points or locations must be explained in the QAPP.

For each matrix, a detailed rationale for selection of the sampling design should be provided, including critical and background sample locations. The QAPP should describe the logic used to determine sample locations, analytical groups, and concentration levels, as well as the type, number, and frequency of field samples and field QC samples to be collected (include statistical tests used, conceptual site models, etc.). If software products, such as Visual Sample Plan (VSP), are used to provide project-specific, statistically derived rationales, the QAPP must document the name and version number of the software and describe how it will be used to determine the sampling design. QAPP Worksheet #17 may be used to present this information.

Examples of the information to be provided on the selection of sampling locations include:

- The basis for selecting the size of the grid, if a grid system will be used to select random sampling locations.
- Decision trees that document the critical decision points of the location selection process, if on-site analytical measurements or screening techniques will be used to identify sample locations.

- The rationale for choosing a nonstatistical approach, if a biased sampling approach will be used to select sampling locations.
- The criteria for selecting "hot spots," if biased or judgmental sampling will be performed.

Additional information to explain the sampling design rationale may be necessary, such as compositing rationale and procedures, if samples will be composited.

Selected sample locations should be identified and documented on additional site maps, charts, and plans. An SOP should be attached or referenced that documents how the sampling points or locations will be precisely determined, for example by using a geographic information system (GIS), global positioning system (GPS), or physical markers, and if used, the GIS that will be used to store and display site information. Site maps should include the site borders, well boring, and test pit installations from previous investigations; areas with known or suspected oil or chemical spills or toxic substance releases; and buildings, hills, water bodies, depressions, etc.

Figure 23 (QAPP Worksheet #18) provides an example summary table. Selected information needed to complete this table is discussed in Section 3.1.2 of this Manual. Only a short reference for the sampling location rationale is necessary for the table, such as background, grid, hot spot, downgradient of release, VSP output, representativeness, or completeness. The text of the QAPP should clearly identify the detailed rationale associated with each reference.

Sample Location/ID Number	Matrix	Depth (units)	Analytical Group	Concentration Level	Number of Samples (identify field duplicates)	Sampling SOP Reference[1]	Rationale for Sampling Location
MW-1	*GW*	*20-30 ft*	*VOA*	*Low*	*1*	*S-1*	*Background*
			SVOC	*Low*	*1*	*S-2*	

[1]Specify the appropriate reference letter or number from the Project Sampling SOP References table (Figure 21).

Figure 23. Example Sampling Locations and Methods/SOP Requirements (QAPP Worksheet #18)

Graded Approach

For a site with a large number of sample locations or ID numbers, the range of location or ID numbers can be grouped by similar matrix, analytical group, or concentration level.

A summary of the analytical SOP requirements should be provided (see Figure 24, QAPP Worksheet #19), and the QAPP should document the rationale for selecting the sample volume, container, preservation, and holding times requirements (e.g., EPA method or regulation). Information needed

to complete this table is discussed in Sections 3.1.2 and 3.2 of this Manual. Information concerning sample containers, volume, and preservation is discussed in Section 3.1.2.2.

Matrix	Analytical Group	Concentration Level	Analytical and Preparation Method/ SOP Reference[1]	Sample Volume	Containers (number, size, and type)	Preservation Requirements (chemical, temperature, light protected)	Maximum Holding Time (preparation/ analysis)

[1]Specify the appropriate reference letter or number from the Analytical SOP References table (Figure 23).

Figure 24. Analytical SOP Requirements (QAPP Worksheet #19)

The number of field QC samples for each matrix, analytical group, and concentration level should also be provided (see Figure 25, QAPP Worksheet #20). The QAPP should document the rationale for selecting the number and type of field QC samples (e.g., EPA method or regulation), provide a complete detailed description of the analytical tasks and associated analytical control, and identify all analytical SOPs and methods in the appropriate sections of the QAPP (see Sections 3.2.1 and 3.4).

Matrix	Analytical Group	Concentration Level	Analytical and Preparation SOP Reference[1]	No. of Sampling Locations[2]	No. of Field Duplicate Pairs	Inorganic	No. of Field Blanks	No. of Equip. Blanks	No. of PT Samples	Total No. of Samples to Lab
						No. of MS				

[1]Specify the appropriate reference letter or number from the Analytical SOP References table (Figure 23).
[2]If samples will be collected at different depths at the same location, count each discrete sampling depth as a separate sampling location or station.

Figure 25. Field Quality Control Sample Summary (QAPP Worksheet #20)

3.1.2 Sampling Procedures and Requirements

All sampling procedures that will be used in the project must be documented in the QAPP or attached documents. Attachments must be provided with or referenced in the QAPP to allow for review and approval. Standardized sampling procedures provide consistency between samplers; facilitate collection of accurate, precise, and representative samples; and help to ensure data comparability and usability. Although it may be possible to comprehensively describe the sampling procedures for small projects within the text of the QAPP, the most efficient and cost-effective way to document project-specific sampling techniques is to include sampling SOPs as attachments to the QAPP.

Sampling procedures should include SOPs for sampling each matrix and each analytical parameter for each type of equipment and technique. The SOPs must detail the appropriate number, size, and

type of sample containers to be used for collection of each field sample and field QC sample and the proper temperature, light, and chemical preservation procedure for those samples.

> **Note:** All project sampling SOPs must be listed~~,~~ including, but not limited to, sample collection, sample preservation, equipment cleaning and decontamination, equipment testing, inspection and maintenance, supply inspection and acceptance, and sample handling and custody SOPs.

The QAPP should provide a table that contains the information shown in Figure 26 (QAPP Worksheet #21). Sequentially number sampling SOP references in the Reference Number column. The reference number can be used throughout the QAPP to refer to a specific SOP.

Reference Number	Title, Revision Date, and/or Number	Originating Organization	Equipment Type	Modified for Project Work? (Y/N)	Comments

Figure 26. Project Sampling SOP References (QAPP Worksheet #21)

3.1.2.1 <u>Sample Collection Procedures</u>

The QAPP must describe how samples will be collected. The selected sample collection procedures must be appropriate to ensure that project personnel collect representative samples in a consistent manner for all required sample matrices and locations, that contamination is not introduced during collection, and that sample volumes are properly preserved in order to meet project objectives.

3.1.2.2 <u>Sample Containers, Volume, and Preservation</u>

The QAPP should include a description of preservation procedures (temperature, light, chemical) that maintain sample integrity in the field, prior to and during shipment to, and immediately upon receipt by, the off-site or mobile on-site laboratory. The QAPP should document requirements for sample volumes, container types, numbers of containers, and preservation procedures for each analytical group, matrix, and concentration level (see Figure 24, QAPP Worksheet #19).

3.1.2.3 <u>Equipment/Sample Containers Cleaning and Decontamination Procedures</u>

The QAPP should provide details on the procedures for both the initial cleaning of sampling equipment *and* subsequent decontamination procedures that will be followed during the sampling event. These procedures will help ensure that collected samples are representative of the sampling location by verifying that sampling equipment is clean and free of target analytes/COCs or interferences. Cleaning and decontamination procedures should cover all equipment that contacts

a sample. If the sampling equipment is disposable ("one use only"), procedures for cleaning and decontamination are not necessary; however, the QAPP should state that disposable equipment will be used.

3.1.2.4 Field Equipment Calibration, Maintenance, Testing, and Inspection Procedures

The QAPP should describe all procedures and documentation activities that will be performed to ensure that field sampling equipment is available and in working order when needed; that all field equipment, including tools, gauges, pumps, etc., are calibrated to perform within specified limits; and that corrective action is taken to fix problems prior to and during field operations. The procedures should include record-keeping for documenting field equipment calibration, maintenance, testing, and inspection activities and discuss the availability of spare parts and equipment to ensure that project schedules are met. Figure 27 (Worksheet #22) shows what information to include in the Field Equipment Calibration, Maintenance, Testing, and Inspection table. The information provided should demonstrate the ability of the equipment to collect appropriate samples and data during field operations. All field equipment (other than analytical instrumentation) should be listed, including but not limited to tools, gauges, and pumps.

Field Equipment	Calibration Activity	Maintenance Activity	Testing Activity	Inspection Activity	Frequency	Acceptance Criteria	Corrective Action	Responsible Person	SOP Reference[1]

[1]Specify the appropriate reference letter or number from the Project Sampling SOP References table (Figure 21).

Figure 27. Field Equipment Calibration, Maintenance, Testing, and Inspection (QAPP Worksheet #22)

3.1.2.5 Sampling Supply Inspection and Acceptance Procedures

The QAPP should document the procedures and activities that will be performed to ensure that all sampling supplies are free of target analytes/COCs and interferences and provide inspection and acceptance requirements for any supplies or consumables that could affect data quality. The documentation should include the following:

- Supplies that will be used during sampling
- All vendors for supplies and reagents
- Specifications for all supplies and reagents that could affect data quality (such as level of contamination, pesticide versus reagent-grade).
- Procedures that will be used to ensure supply cleanliness and reagent purity (such as recording reagent lot numbers)
- Procedures for measuring supply cleanliness
- Corrective action procedures for preventing the use of unacceptable supplies

The individuals responsible for checking supplies and implementing corrective actions should be identified. This information may be contained in an SOP attached to or referenced in the QAPP.

3.1.2.6 Field Documentation Procedures

To provide a permanent record of field activities and possible introduction of sampling error, observations and measurements taken in the field must be recorded. Typically, field data are recorded in field logbooks, on field data collection forms, or electronically.

As part of the overall project data tracking and management system (described in Section 3.5), the QAPP should describe the field documentation tracking and management system. For example, the title of each field notebook should indicate its function, and each notebook used for a specific site or project should be referenced to all the other project notebooks, including the project manager's daily log. Also, each notebook should be tracked and archived with other project records in accordance with the project data management system.

Since field information depends on the specific matrix and procedure, the QAPP should describe the field information that will be recorded for each matrix and each type of sampling procedure. If field data collection forms will be used, examples of the forms should be included as figures in the QAPP or as attachments to the QAPP, and the forms referenced (this also applies to electronic forms). If field notebooks will be used, the requirements for the notebooks should be described in the QAPP. Bound notebooks with water-resistant, sequentially numbered pages and indelible ink entries should be used.

Regardless of the means used to record sampling information, copies of field data records should be included with the associated data review reports to facilitate the identification of sampling error.

3.2 Analytical Tasks

The following sections address all components of the project-specific analytical measurement system, including on-site and off-site laboratory analytical SOPs; method- and laboratory-specific QC measurements, acceptance criteria, and corrective actions; calibration procedures; and instrument, equipment, and supply maintenance, testing, and inspection requirements. The following sections apply to both on-site and off-site analytical procedures. Different types of analyses can be addressed in separate sections within the QAPP.

On-site analysis includes both semiquantitative and semiqualitative field screening techniques and definitive analytical methods. Definitive data may be generated for field parameters, including specific conductance, temperature, dissolved oxygen, pH, turbidity, and oxidation/reduction potential using field instrumentation. Definitive inorganic and organic data may be generated in a

mobile on-site laboratory equipped with a gas chromatograph (GC), gas chromatograph/mass spectrometer (GC/MS), inductively coupled plasma (ICP), etc.

> **Screening and Definitive Data**
>
> Screening data may be used to support intermediate decisions, while only definitive data may be used to support final decisions.

The QAPP should differentiate between screening procedures and procedures used to generate definitive data. Definitive data can be generated by a field method, an on-site laboratory, or an off-site laboratory. If definitive data will be generated in the field, documentation (e.g., a QA plan, SOP, sampling and analysis plan, field QA plan) must be referenced or attached to the QAPP. If definitive data will be generated by a laboratory (on-site or off-site), the equivalent of a laboratory QA plan should be provided as an attachment to the QAPP. This document may not be necessary if only screening data are being generated. However, the SOPs for generating screening data must be referenced in the QAPP, and they must be available to the personnel performing the screening and the reviewer upon request. If the analytical procedures are documented in the laboratory's QA plan or manual, it may be easiest to reference the appropriate sections of those documents or include only the relevant sections in the QAPP. This would eliminate the need to include separate analytical SOPs (assuming that those relevant sections of the laboratory's QA plan contain all of the required information). Laboratory QA plans or manuals must be included for each laboratory retained for analytical services.

The QAPP must provide sufficient documentation to assure the reviewer that accurate, precise, and usable data will be generated and that preventive and corrective action plans are in place prior to the initiation of the sampling event.

> **Contracting Services**
>
> All contracted or subcontracted on-site analytical and off-site laboratory services should be in place before the final QAPP is approved.

Where contractual, regulatory, or programmatic requirements specify that a laboratory be accredited, documentation of the laboratory accreditation should be included as an attachment to the QAPP.

The QAPP should describe the analytical techniques that will be used to generate screening and definitive data for the project. It also should document the analytical SOPs that will be used to meet measurement performance criteria and achieve project-required QLs for the target analytes/COCs at target concentration levels and in specific matrices.

3.2.1 Analytical SOPs

Methods Versus Analytical SOPs

Note the difference between methods and analytical SOPs: Methods are published procedures that describe preparatory and analytical determinative techniques used in target analyte identification and quantitation. Analytical SOPs document how a particular laboratory will perform a specific analytical method.

All analytical procedures that will be used in the project must be documented in the QAPP or attached document(s) to allow for review and approval. Attachments must be provided with or referenced in the QAPP. Although it may be possible to describe simple analytical procedures within the text of the QAPP, the most efficient and cost-effective way to document project-specific measurement procedures is to include analytical SOPs as attachments to the QAPP. The QAPP should include SOPs and reference the methods they are based on for each analytical group, matrix, and concentration level that will be investigated. Proprietary SOPs may be submitted as confidential business information. All SOPs must specify the maximum allowable holding time from sample collection to sample preparation or analysis, as appropriate.

Figure 28 (QAPP Worksheet #23) shows what information on analytical SOPs to include in the references table. References to analytical SOPs should be sequentially numbered in the Reference Number column. The reference number can be used throughout the QAPP to refer to a specific SOP.

Reference Number	Title, Revision Date, and/or Number	Definitive or Screening Data	Analytical Group	Instrument	Organization Performing Analysis	Modified for Project Work? (Y/N)

Figure 28. Analytical SOP References (QAPP Worksheet #23)

3.2.2 Analytical Instrument Calibration Procedures

To ensure that the analytical methods and the selected instrumentation meet the project requirements for selective, sensitive, accurate, and precise detection and quantitation of the analytes of interest, it is necessary to describe completely the calibration procedures for each analytical instrument, as well as demonstrate the ability of the analytical technique to accurately and precisely identify and quantitate the target analytes/COCs at the required QLs and within the required measurement ranges.

All instruments must be calibrated according to a schedule specified by the method and instrument manual or SOPs. Calibration procedures may be documented separately in the QAPP or cross-referenced and included with the analytical SOPs as attachments to the QAPP.

The QAPP should contain the information shown in Figure 29 (QAPP Worksheet #24) and a list of all analytical instrumentation should be provided.

Instrument	Calibration Procedure	Frequency of Calibration	Acceptance Criteria	Corrective Action (CA)	Person Responsible for CA	SOP Reference[1]

[1]Specify the appropriate reference letter or number from the Analytical SOP References table (Figure 23).

Figure 29. Analytical Instrument Calibration (QAPP Worksheet #24)

3.2.3 Analytical Instrument and Equipment Maintenance, Testing, and Inspection Procedures

The QAPP should describe the procedures and documentation activities that will be performed to ensure that all analytical instrumentation and equipment are available and in working order when needed. The QAPP should contain the information shown in Figure 30 (QAPP Worksheet #25).

Instrument and equipment maintenance logs must be kept to document analytical instrumentation and equipment maintenance, testing, and inspection activities.

The QAPP should discuss the ability to ensure that project schedules are met (e.g., availability of spare parts or spare instruments, instrument control (on-site and during storage), security, and availability (e.g., log-in/log-out procedures)).

Instrument/ Equipment	Maintenance Activity	Testing Activity	Inspection Activity	Frequency	Acceptance Criteria	Corrective Action	Responsible Person	SOP Reference[1]

[1]Specify the appropriate reference letter or number from the Analytical SOP References table (Figure 23).

Figure 30. Analytical Instrument and Equipment Maintenance, Testing, and Inspection (QAPP Worksheet #25)

3.2.4 Analytical Supply Inspection and Acceptance Procedures

The QAPP should document the procedures and activities that will be performed to ensure that all supplies used in analytical work will be available when needed and will be free of target analytes/COCs and interferences. The documentation should include the following:

- Supplies that will be used in the performance of analytical work
- All vendors for supplies and reagents
- Specifications for all supplies and reagents that could affect data quality (such as level of contamination, pesticide versus reagent-grade). Procedures that will be used to ensure supply cleanliness and reagent purity (such as recording reagent lot numbers)
- Procedures for measuring supply cleanliness

- Corrective action procedures for preventing the use of unacceptable supplies

The individuals responsible for checking supplies and implementing corrective actions should be identified. This information may be contained in an SOP attached to or referenced in the QAPP.

3.3 Sample Collection Documentation, Handling, Tracking, and Custody Procedures

The QAPP must include all sample collection documentation and sample handling, tracking, and custody procedures used to ensure that sample integrity and custody are maintained. The procedures should address sample collection, packaging, handling, and shipping, as well as records, receipt of laboratory samples, archiving, and disposal. Chain-of-custody SOPs should include those procedures associated with sampling and on-site and off-site laboratory analysis. The procedures may be included as attachments, and cross-referenced in the QAPP.

3.3.1 Sample Collection Documentation

Proper field sampling and on-site and off-site analytical documentation help ensure sample authenticity (i.e., the sample identity is correct) and data integrity. On-site analytical and off-site laboratory documentation procedures are discussed in Section 3.5, in conjunction with data management and project records. The QAPP should describe sample documentation procedures that will be followed for the project.

Documentation for sample collection includes sample container identification. The QAPP should specify the required sample identification information and include an example. An electronic system, such as a bar code or FORMS II Lite (which retrieves information stored elsewhere), may be used. The QAPP should describe how the information on the label will be preserved (e.g., by covering the label with clear tape to minimize water damage during transit). Refer to Section 3.1.2.6 for information about field documentation (e.g., field logbooks, field data collection forms) procedures.

3.3.2 Sample Handling and Tracking System

Proper sample tracking systems support the chain-of-custody procedures, which in turn help to ensure sample authenticity and data defensibility. The QAPP should document the procedures that will be followed to identify and track samples that are collected in the field, analyzed on-site, and delivered or shipped to an off-site laboratory for analysis, as well as samples transferred throughout the laboratory. If samples are shipped to an off-site laboratory, then the laboratory's sample handling and tracking system should also be described.

The sample handling and tracking procedures should do the following:

- **Describe the sample numbering system for field sample collection and provide an example.** If applicable, the numbering system should follow specific programmatic requirements that apply to the project. A systematic approach for numbering samples should be used so that each sampling location, matrix type, sample depth or height, and date and time of collection can be uniquely identified and cross-referenced to the programmatic sample number.

- **Describe the sample container identification information.** See Appendix A, Section A.3.1.

- **Describe the laboratory sample tracking procedures.** If laboratory identification numbers will be used to track samples internally, the laboratory procedure must describe how these laboratory identification numbers will be cross-referenced with the sample number assigned in the field.

- **Describe sample storage procedures used by the off-site or mobile on-site laboratory.**

3.3.2.1 Sample Handling

To demonstrate the project's sample handling process, the QAPP should include a table that shows the flow of samples from the time of collection to laboratory delivery to final sample disposal (see Appendix A, QAPP Worksheet # 26, for an example). The table should identify each component of the project-specific sample handling system; indicate the personnel (and their organizational affiliations) who are primarily responsible for ensuring proper sample handling, custody, storage, and disposal; and specify the length of time that samples, digestates and extracts, and biological collections will be retained by the laboratory prior to disposal.

3.3.2.2 Sample Delivery

The QAPP should describe how samples will be delivered or shipped to the laboratory. The description should include the name of the carrier service, if applicable, and define how samples will be batched or grouped when sent to the laboratory. Samples can be grouped in sample delivery groups (SDGs), defined as a group of 20 or fewer field samples within a project. Proficiency testing samples and other field QC samples (e.g., equipment blanks, volatile organic analytes [VOA] trip blanks) are counted as field samples in the 20-sample SDG total.

The QAPP should include provisions for packaging, marking and labeling, and shipping samples in compliance with the most recent U.S. Department of Transportation regulations for shipping hazardous and nonhazardous materials. Air carriers that transport hazardous materials require compliance with the current edition of the International Air Transport Association Dangerous Goods Regulations, which applies to shipment and transportation of hazardous materials by air carriers. Shipment papers, including bills of lading and airbills, should be retained by the laboratory with chain-of-custody records. Examples of all sample shipment forms to be used should be included. These may be the same as the chain-of-custody forms, which are discussed in Section 3.3.3.

3.3.3 Sample Custody

A sample is in "custody" if it is in the actual physical possession of authorized personnel or in a secured area that is restricted to authorized personnel. For some projects, an evidentiary paper trail documenting sample custody is required in order to meet project quality objectives. Since it is often difficult to predict what samples or projects will require proof of custody after the fact, all data collection events should employ documented chain-of-custody procedures to ensure data authenticity and defensibility.

> **Note:** Only through complete documentation can the end-user prove that the individual sample results reflect a particular sample (collected at a specific location at a specific date and time) and that the sample was handled as prescribed.

The QAPP should describe the procedures that will be used to maintain sample custody and integrity and to document the implementation of chain-of-custody procedures. QAPP Worksheet #27 may be used to present sample custody information. The evidentiary trail from sample collection through data generation and archiving is maintained using sample custody procedures and documented by complete chain-of-custody records.

Chain-of-custody procedures ensure accountability for the location and integrity of the sample at all times.(The ASTM document *D4840-99 Standard Guide for Sampling Chain-of-Custody Procedures* contains information regarding chain-of-custody procedures.)

Sample custody procedures should include the field sampling team's procedures for maintaining and documenting sample custody from the time samples are collected in the field through packaging, shipment, and delivery to the laboratory. Field sampling documents that describe chain-of-custody procedures, including SOPs, should be attached to or referenced in the QAPP. The laboratory's procedures for maintaining and documenting sample custody from the time the samples are received at the laboratory through archiving and disposal should also be attached to or referenced in the QAPP. The use of software, such as FORMS II Lite, must be documented, if applicable.

Examples of all chain-of-custody documentation that will be used during the project should be provided in the QAPP, including chain-of-custody forms, traffic reports, sample identification, custody seals, laboratory sample receipt forms, laboratory sample transfer forms, etc.

3.4 Quality Control Samples

This section addresses quality control samples only. Quality control (QC) is the set of activities that are performed for the purposes of monitoring, measuring, and controlling the performance of a measurement process. QC samples provide measurable data quality indicators used to evaluate the different components of the measurement system, including sampling and analysis.

During the systematic planning process, each QC sample's value should be determined based on its contribution to measuring precision, accuracy/bias, contamination, and sensitivity. QC samples may impose significant costs; therefore, it is important to identify which of those samples are not cost-effective (i.e., which provide little additional information regarding data quality, or which duplicate information provided by other QC samples). Project QC needs must be determined based on the decision to be made and the related level of data quality required. Deciding the most appropriate QC samples and setting appropriate acceptance limits are a key part of project planning and frequently require some professional judgment.

QA/QC Compendium

Part 2B of the UFP-QAPP, the QA/QC Compendium, provides background material to this Manual. The Compendium identifies as minimum activities those QC samples that either provide the most reliable information on overall data quality or identify specific sources of error. See Section 2.2 of the Compendium for further rationale for QC sample selection. **Note:** Many QC samples that are standard requirements in analytical methods are listed in Tables 4 and 5 but are not included in the QA/QC Compendium.

Many (but not all) analytical methods will also specify QC practices. The minimum QC activities for screening and definitive data collected for use in the CERCLA process are provided in the Compendium. These activities may be appropriate for other environmental programs.

Tables 4 and 5 provide examples of QC samples that are frequently incorporated into chemical data collection and analysis activities. Samples that commonly originate in the field are listed in Table 4; samples that are usually initiated in the laboratory are listed in Table 5. The QC needs for each sampling project are unique. Although Tables 4 and 5 contain the most frequently run QC samples, not all samples are applicable to every analytical procedure. Those QC samples that are minimum activities identified in Part 2B of the UFP-QAPP are identified.

Table 4. Recommended Types and Frequency of Sampling QC Samples for Chemical Data Collection

Sampling QC[1]	Data Quality Indicator[2]	Recommended Frequency
Field Blank (including VOA Trip Blank)[3]	Contamination (Accuracy/Bias)	Minimum 1 per shipment cooler per analytical group per concentration level
Equipment Blank (rinsate blank)[3]	Contamination (Accuracy/Bias)	Minimum 5% per analytical group per matrix per sampling procedure per sampling team

Table 4. Recommended Types and Frequency of Sampling QC Samples for Chemical Data Collection (continued)

Sampling QC[1]	Data Quality Indicator[2]	Recommended Frequency
Proficiency Testing Sample[3, 4]	Accuracy/Bias	Minimum 1 per SDG per analytical group per matrix per concentration level
Field Duplicates – Co-located Samples[3] – Subsamples	Precision	Minimum 5% per analytical group per matrix per sampling procedure per sampling team
Split Samples	Interlaboratory Comparability	As specified by method and based on PQOs

[1]Co-located and analyzed to measure errors introduced during sampling and other field activities.
[2]See Table 6 for additional DQI information.
[3]Minimum QC activity from Part 2B of the UFP-QAPP.
[4]Proficiency testing samples have been included under field sampling QC samples since they may be introduced during that stage. They primarily measure analytical error, since their composition is unknown to the laboratory and they originate outside of the laboratory.

Table 5. Recommended Types and Frequency of Analytical QC Samples for Chemical Data Collection

Analytical QC	Data Quality Indicators[1]	Recommended Frequency
Method Blank	Accuracy/Bias (Contamination)	Minimum 1 per SDG per analytical group per matrix per concentration level
Instrument (System) Blank	Accuracy/Bias (Contamination)	As specified by method and based on
Laboratory Duplicates[2]	Precision	Minimum 1 per inorganic SDG per analytical group per matrix per concentration level
Internal Standards	Precision and Accuracy/Bias	As specified by method and based on PQOs
Matrix Spike (inorganics only)[2]	Bias	Minimum 1 per inorganic SDG per analytical group per matrix per concentration level
PT Sample – Single Blind and Double Blind[2]	Bias	Minimum 1 per SDG per analytical group per matrix per concentration level
Surrogate Spikes	Bias	As specified by method and based on PQOs
Laboratory Control Sample (LCS)	Bias	As specified by method and based on PQOs

Table 5. Recommended Types and Frequency of Analytical QC Samples for Chemical Data Collection (continued)

Analytical QC	Data Quality Indicators[1]	Recommended Frequency
Laboratory Fortified Blank (LFB)	Bias and Sensitivity	Minimum 1 per aqueous low-concentration organic SDG/analytical group As specified by method and based on PQOs for other analytical groups, matrices, and concentration levels
Instrument Performance Check Samples	Sensitivity	As specified by method and based on PQOs
Initial Calibration	Accuracy	After initial instrument setup, as specified by method and when calibration verification fails
Continuing Calibration or Calibration Verification Checks	Accuracy	Minimum 1 per analytical shift and more frequently as specified by method and based on PQOs

[1]See Table 6 for additional DQI information.
[2]Minimum QC activity from Part 2B of the UFP-QAPP.

Table 6 provides a more extensive list of QC samples and summarizes the information derived from different sampling, transportation, and laboratory QC samples. QC samples that provide the best overall measure of data quality and identify critical sources of error are recommended in the table. Other QC samples may be appropriate on some projects but should not be considered minimum samples for every project.

3.4.1 Sampling Quality Control Samples

To monitor the quality of various aspects of the sampling event, the QAPP should identify the QC samples and their respective acceptance limits for the project. The QAPP should also document the required analysis frequency and corrective actions (see Figure 31, QAPP Worksheet #28). This information should correspond with Figure 14 in Section 2.6.2, which identifies the QC samples associated with the selected measurement performance criteria.

Table 4 provides a list of recommended sampling QC samples. However, actual types and frequencies are determined during planning based on project-specific needs.

3.4.2 Analytical Quality Control Samples

The QAPP should identify the QC samples, and their respective acceptance limits, that will be used during the project to monitor the quality of various preparatory and analytical steps and should

Table 6. Information Derived from Quality Control Samples

Data Quality Indicator (Type of Information Provided)	QC Samples	Sources of Measurement Error										Purpose	Recommended*
		Sample Collection				Sample Transport	Laboratory						
		Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Shipment Process	Sample Storage at Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment		
Accuracy/Bias (Contamination)	**Field Blank**	X	X	X	X	X	X	X	X	X	X	To evaluate contamination introduced during sampling, storage, and transport.	T
	Equipment Blank (rinsate blank)	X	X	X		X	X	X	X	X	X	To evaluate carryover contamination resulting from successive use of sampling equipment.	T
	Bottle Blank per Lot #		X					X	X	X	X	To evaluate contamination introduced from the sample container.	
	VOA Trip Blank		X	X		X	X	X	X	X	X	To evaluate contamination introduced during shipment.	
	Storage Blank						X	X	X	X	X	To evaluate cross-contamination introduced during sample storage.	

Table 6. Information Derived from Quality Control Samples (continued)

Data Quality Indicator (Type of Information Provided)	QC Samples	Sources of Measurement Error										Purpose	Recommended*
		Sample Collection				Sample Transport	Laboratory						
		Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Shipment Process	Sample Storage at Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment		
Accuracy/Bias (Contamination) (continued)	**Method Blank**							X	X	X	X	To evaluate contamination introduced during sample preparation or analysis by laboratory, including reagents, equipment, sample handling, and ambient laboratory conditions.	T*
	Reagent Blank per Lot #							X	X	X	X	To evaluate contamination introduced by specific method reagents.	
	Instrument (System) Blank									X	X	To evaluate contamination originating from the analytical reagents instrumentation.	T
Accuracy/Bias (Preservation)	**Cooler Temperature Blank**			X								To evaluate whether or not samples were adequately cooled during shipment.	
Accuracy/Bias	**Matrix Spike – Inorganics Only**				X			X	X	X	X	To determine laboratory preparatory and analytical bias for specific compounds in specific sample matrices.	T

Table 6. Information Derived from Quality Control Samples (continued)

Data Quality Indicator (Type of Information Provided)	QC Samples	Sources of Measurement Error										Purpose	Recommended*
		Sample Collection				Sample Transport	Laboratory						
		Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Shipment Process	Sample Storage at Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment		
Accuracy/Bias (continued)	**Surrogate Spike – Organics Only**				X			X	X	X	X	To evaluate laboratory preparatory and analytical bias for specific sample matrices.	T*
	Laboratory Control Sample (LCS)							X	X	X	X	To evaluate the laboratory's ability to accurately identify and quantitate target compounds in a reference matrix at a known concentration, usually midrange of the calibration curve.	T

Table 6. Information Derived from Quality Control Samples (continued)

Data Quality Indicator (Type of Information Provided)	QC Samples	Sources of Measurement Error										Purpose	Recommended*
		Sample Collection				Sample Transport	Laboratory						
		Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Shipment Process	Sample Storage at Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment		
Accuracy/Bias (continued)	**Proficiency Testing Sample – Ampulated Single Blind**							X	X	X	X	To evaluate sample handling procedures from field to laboratory. To evaluate the laboratory's ability to accurately identify and quantitate target compounds in a reference matrix. Frequently used for data review and for laboratory self-assessments and external assessments, i.e., preawards and laboratory technical system audits (TSAs).	
	Proficiency Testing Sample – Full Volume Single Blind		X	X		X	X	X	X	X	X		
	Proficiency Testing Sample – Double Blind		X	X		X	X	X	X	X	X	To evaluate sample handling procedures from field to laboratory. To evaluate the laboratory's ability to accurately identify and quantitate target compounds in a reference matrix.	T

Table 6. Information Derived from Quality Control Samples (continued)

Data Quality Indicator (Type of Information Provided)	QC Samples	Sources of Measurement Error: Sample Collection: Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Sample Transport: Shipment Process	Laboratory: Sample Storage at Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment	Purpose	Recommended*
Accuracy/Bias (continued)	Laboratory Fortified Blank (LFB)							X	X	X	X	A type of LCS used to evaluate laboratory (preparatory and analytical) sensitivity and bias for specific compounds in a reference matrix at QL concentrations.	T
	Initial Calibration									X	X	To ensure that the instrument is capable of producing acceptable qualitative and quantitative data.	T
	Continuing Calibration/ Continuing Calibration Verification									X	X	To ensure the accuracy and stability of the instrument response.	T
	Instrument Performance Check Sample									X	X	To verify that an instrument can accurately identify and quantitate target analytes at specific concentration levels.	T

Table 6. Information Derived from Quality Control Samples (continued)

Data Quality Indicator (Type of Information Provided)	QC Samples	Sources of Measurement Error										Purpose	Recommended*
		Sample Collection				Sample Transport	Laboratory						
		Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Shipment Process	Sample Storage at Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment		
Sensitivity	**Laboratory Fortified Blank**							X	X	X	X	A type of LCS used to evaluate laboratory (preparatory and analytical) sensitivity and bias for specific compounds in a reference matrix at QL concentrations.	T
	MDL Studies				X (if performed using same reference matrix)			X	X	X	X	A statistical determination that defines the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero. QLs/practical QLs (PQLs) are generally 3-10 times the method detection limit (MDL).	

Table 6. Information Derived from Quality Control Samples (continued)

Data Quality Indicator (Type of Information Provided)	QC Samples	Sources of Measurement Error										Purpose	Recommended*
		Sample Collection				Sample Transport	Laboratory						
		Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Shipment Process	Sample Storage at Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment		
Sensitivity (continued)	**Low Point of Initial Calibration Curve**									X	X	To ensure that the instrument is capable of producing acceptable qualitative and quantitative data at the lowest concentration that sample results will be reported; the quantitation limit.	T
Precision	**Field Duplicates**	X	X	X	X	X	X	X	X	X	X	To measure overall precision by evaluating cumulative effects of both field and laboratory precision.	T
	Laboratory Duplicates				X			X	X	X	X	To evaluate laboratory preparatory and analytical precision.	T*
	Matrix Spike Duplicates				X			X	X	X	X	To determine laboratory preparatory and analytical bias and precision for specific compounds in specific sample matrices.	
	Analytical Replicates (e.g., duplicate injections)										X	To evaluate analytical precision for determinative instrumentation.	

Data Quality Indicator (Type of Information Provided)	QC Samples	Sources of Measurement Error										Purpose	Recommended*
		Sample Collection				Sample Transport	Laboratory						
		Sampling Equipment	Sample Container	Preservation Technique	Sample Matrix	Shipment Process	Sample Storage at Laboratory	Sample Preparation Reagents	Sample Preparation Equipment	Analytical Method Reagents	Analytical Equipment		
Precision (continued)	**Internal Standards**										X	To evaluate instrument precision and stability.	T
Interlaboratory Comparability	**Split Samples**					X	X	X	X	X	X	To evaluate sample handling procedures from field to laboratory and to evaluate interlaboratory comparability and precision.	T
Reproducibility	**Biological QC Check**	X	X	X		X	X	X	X	X	X	To evaluate biological sorting reproducibility between laboratories or analysts.	T

*The samples without "Recommended" checkmarks are believed to provide redundant QC data and raise the project's analytical costs.

identify the project personnel expected to perform the QC activities. In addition, the QAPP must include the following:

- An explicit description of the QC samples to be collected/analyzed
- A required frequency at which it must be collected
- A description, usually in mathematical terms, of what constitutes acceptable performance for the QC sample
- Corrective actions to be taken if the QC sample fails these criteria
- A description of how the QC data and results are to be documented and reported to the data user

Note: Many analytical methods provide QC acceptance limits for most of the QC samples required by those methods. Certain methods require that laboratories generate their own specific QC acceptance limits for the QC samples required. These method- and laboratory-specific limits, however, may not be "tight" enough to support the project quality objectives. In other words, QC sample results may meet method/SOP QC acceptance limits but fail to meet the measurement performance criteria of the project as defined and documented in Section 2.6.2. Therefore, it is important to select analytical methods having QC acceptance limits that support the collection and analysis of usable project data. Subsequently, choosing a laboratory that is capable of meeting the project-required QC acceptance limits is critical. Again, method- and laboratory-specific QC acceptance limits, project measurement performance criteria, and project review criteria must be complementary for project objectives to be achieved.

For some projects, the selected analytical method may not have sufficient QC samples built into the method. In those cases, the project team will need to specify what additional QC samples must be analyzed by the laboratory. The laboratory should document additional project-required QC activities in its analytical SOPs, along with the required frequency, acceptance criteria, and corrective actions for those QC samples.

Table 5 lists types of analytical QC samples but does not include all possible QC samples that are available to the user. Also, analytical methods may define the purpose of specific QC samples differently (e.g., dioxin methodologies); therefore, it is necessary to adhere to the QC definitions of the specific methods used.

The QAPP should contain the information shown in Figure 31 (QAPP Worksheet #26), including both sampling and analytical QC samples. This information should correspond with Figure 14 in Section 2.6.2, which identifies the QC samples associated with selected measurement performance criteria.

If screening analyses are performed, a decision tree or logic diagram should be provided to describe how samples will be selected for subsequent confirmation with definitive data analysis (see Section 2.6.2.5.2). If method/SOP QC acceptance limits exceed the project-specific measurement performance criteria, the data obtained may be unusable for making project decisions.

Matrix						
Analytical Group						
Concentration Level						
Sampling SOP						
Analytical Method/ SOP Reference						
Sampler's Name						
Field Sampling Organization						
Analytical Organization						
No. of Sample Locations						
QC Sample:	**Frequency/Number**	**Method/SOP QC Acceptance Limits**	**Corrective Action**	**Person(s) Responsible for Corrective Action**	**Data Quality Indicator (DQI)**	**Measurement Performance Criteria**

Figure 31. QC Samples
(QAPP Worksheet #28)

3.5 Data Management Tasks

All project data and information must be documented in a format that is usable by project personnel. Therefore, the QAPP should describe how project data and information will be documented, tracked, and managed, from generation in the field to final use and storage, in a manner that ensures data integrity, defensibility, and retrieval. If electronic data is required, the QAPP should specify the requirements.

3.5.1 Project Documentation and Records

All project documents and records that will be generated for every aspect of the project should be identified in the QAPP. These include but are not limited to the following:

1. Sample Collection and Field Measurement Records

- Field data collection sheets
- Chain-of-custody records
- Airbills
- Communication logs
- Corrective action reports
- Documentation of corrective action results
- Documentation of deviation from methods

- Documentation of internal QA review
- Electronic data deliverables
- Identification of QC samples
- Meteorological data from field (e.g., wind, temperature)
- Sampling instrument decontamination records
- Sampling instrument calibration logs
- Sampling location and sampling plan
- Sampling notes and drilling logs
- Sampling report

2. Analytical Records

- Chain-of-custody records
- Sample receipt forms and sample tracking forms
- Preparation and analysis forms and/or logbooks
- Tabulated data summary forms and raw data for field samples, standards, QC checks, and QC samples
- Case narrative
- Sample chronology (time of receipt, extraction, and analysis)
- Identification of QC samples
- Communication logs
- Corrective action reports
- Definitions of laboratory qualifiers
- Documentation of corrective action results
- Documentation of laboratory method deviations
- Electronic data deliverables
- Instrument calibration reports
- Laboratory name
- Laboratory sample identification numbers
- Reporting forms, completed with actual results
- Signatures for laboratory sign-off (e.g., laboratory QA manager)
- Standards traceability records
- Other project-specific documents in the laboratory's possession, such as telephone logs, MDL studies, initial precision and accuracy tests, laboratory preaward documentation (including preaward PT sample data and relevant copies of proposal package), and corrective action reports

3. Project Data Assessment Records

- Field sampling audit checklists
- Analytical audit checklists
- PT sample results

- Data review reports
- Telephone logs
- Corrective action reports
- Laboratory assessment
- Laboratory QA plan
- MDL study information
- NELAP accreditation

Figure 32 (QAPP Worksheet #29) shows what information to include in the Project Documents and Records table.

Sample Collection Documents and Records	On-site Analysis Documents and Records	Off-site Analysis Documents and Records	Data Assessment Documents and Records	Other

Figure 32. Project Documents and Records (QAPP Worksheet #29)

3.5.2 Data Package Deliverables

The requirements for data package deliverables are project-specific and will vary by analytical group. Table 7 presents examples of laboratory data deliverable elements selected on the basis of analyte group.

3.5.2.1 Sample Collection and Field Measurements Data Package Deliverables

The QAPP should itemize all required elements of data package deliverables for all sample collection activities (see Section 3.5.1 item 1 for examples). If field measurements are taken (e.g., specific conductance, temperature, dissolved oxygen, pH, turbidity, oxidation/reduction potential, and residual chlorine), then all field and QC sample results, calibrations, and calibration verifications should be recorded in a field logbook to ensure proper verification of sample results.

Table 7. Example Analytical Data Deliverable Elements

DATA DELIVERABLE ELEMENTS	VOA	SVOC	PEST/PCB	METALS	CN	OTHER
● INVENTORY SHEET (Org. and Inorg. DC-2 Form)	X	X	X	X	X	X
● NARRATIVE (Org. Narrative, Inorg. Cover Page)	X	X	X	X	X	X
● EPA SHIPPING/RECEIVING DOCUMENTS AND INTERNAL LABORATORY CHAIN-OF-CUSTODY RECORDS:						
- Airbills	X	X	X	X	X	X
- Chain-of-Custody Records/Forms (Traffic Report)	X	X	X	X	X	X
- Sample Tags	X	X	X	X	X	X
- Sample Log-In Sheet (Org. and Inorg. DC-1 Form)	X	X	X	X	X	X
- Miscellaneous Shipping/Receiving Records	X	X	X	X	X	X
- Internal Lab. Sample Transfer Records and Tracking Sheets	X	X	X	X	X	X
● SAMPLE DATA:						
- Tabulated Summary Form for Field Sample and PT Sample Results (Org. and Inorg. Form I)	X	X	X	X	X	X
- Tentatively Identified Compounds Tabulated Summary Form (Org. Form I TIC)	X	X				
- Reconstructed total ion chromatogram (RIC) for each sample	X	X				
- Raw spectra of target compound and background-subtracted spectrum of target compound for each sample	X	X				
- Mass spectra of all reported TICs/three best library matches for each sample	X	X				
- Chromatograms from both columns for each sample			X			
- GC integration report or data system printouts and calibration plots for each sample			X			
- PEST/PCB Identification Tabulated Summary Form (Org. Form X)			X			
- For PEST/PCBs confirmed by GC/MS, copies of raw spectra and background-subtracted spectrum of target compounds			X			
- Gel permeation chromatography sample chromatograms		X	X			
- UFP-QAPP Manual worksheets	X	X	X	X	X	X
- Sample preparation/extraction/digestion log (Inorg. Form XIII) and logbook pages	X	X	X	X	X	X

VOA = volatile organic analytes
SVOC = semivolatile organic compounds
PEST = pesticide organic compounds
PCB = polychlorinated biphenyls
CN = cyanide
Other = other parameters
( ) = Form Number, refer to CLP SOW forms if CLP is used

Table 7. Example Analytical Data Deliverable Elements (continued)

DATA DELIVERABLE ELEMENTS	VOA	SVOC	PEST/PCB	METALS	CN	OTHER
● SAMPLE DATA (continued):						
- Sample analysis run log (Inorg. Form XIV) and logbook pages	X	X	X	X	X	X
- ICP raw data				X		
- Furnace atomic absorption raw data				X		
- Mercury raw data				X		
- Cyanide raw data					X	
- Other analytical raw data						X
● STANDARDS DATA:						
- Method Detection Limit Study Tabulated Summary Form	X	X	X	X	X	X
- Initial Calibration Tabulated Summary Form (Org. Form VI, Inorg. Form IIA)	X	X	X	X	X	X
- Continuing Calibration Tabulated Summary Form (Org. Form VII, Inorg. Form IIA)	X	X	X	X	X	X
- RICs and quantitation reports for all GC/MS standards	X	X				
- Pesticide Analyte Resolution Tabulated Summary Form (Org. Form VI, Pest-4)			X			
- Pesticides Calibration Verification Tabulated Summary Form (Org. Form VII, Pest-1 and Pest-2)			X			
- Pesticide Analytical Sequence Tabulated Summary Form (Org. Form VIII-Pest)			X			
- GC chromatograms and data system printouts for all GC standards			X			X
- For pesticides/aroclors confirmed by GC/MS, copies of spectra for standards used			X			
- GPC Calibration Tabulated Summary Form (Org. Form IX, Pest-2)			X			
- Florisil Cartridge Check Tabulated Summary Form (Org. Form IX, Pest-1)			X			
- Instrument Detection Limits Tabulated Summary Form (Inorg. Form X)				X	X	
- ICP Interelement Correction Factors Tabulated Summary Form (Inorg. Form XIA and XIB)				X		
- ICP Linear Ranges Tabulated Summary Form (Inorg. Form XII)				X		
- CRDL Standards for AA and ICP Tabulated Summary Form (Inorg. Form IIB)				X		
- Standards preparation logbook pages	X	X	X	X	X	X

VOA = volatile organic analytes
SVOC = semivolatile organic compounds
PEST = pesticide organic compounds
PCB = polychlorinated biphenyls
CN = cyanide
Other = other parameters
( ) = Form Number, refer to CLP SOW forms if CLP is used

Table 7. Example Analytical Data Deliverable Elements (continued)

DATA DELIVERABLE ELEMENTS	VOA	SVOC	PEST/PCB	METALS	CN	OTHER
● QC DATA:						
- Tuning and Mass Calibration Tabulated Summary Form (Org. Form V)	X	X				
- Surrogate Percent Recovery Tabulated Summary Form (Org. Form II)	X	X	X			
- MS/MSD Recovery Tabulated Summary Form (Org. Form III)	X	X	X			
- Method Blank Tabulated Summary Form (Org. Form IV and Inorg. Form III)	X	X	X	X	X	
- Internal Standard Area and RT Tabulated Summary Form (Org. Form VIII)	X	X				
- QC Raw Data - RICs, chromatograms, quantitation reports, integration reports, mass spectra, etc.	X	X	X			X
- ICP Interference Check Sample Tabulated Summary Form (Inorg. Form IV)				X		
- Spike Sample Recovery Tabulated Summary Form (Inorg. Form VA)				X	X	
- Post Digest Spike Sample Recovery Tabulated Summary Form (Inorg. Form VB)				X	X	
- Duplicates Tabulated Summary Form (Inorg. Form VI)				X	X	
- Internal Laboratory Control Sample Tabulated Summary Form (Inorg. Form VII)				X	X	
- Standard Addition Results Tabulated Summary Form (Inorg. Form VIII)				X		
- ICP Serial Dilutions Tabulated Summary Form (Inorg. Form IX)				X		
- QC raw data – ICP, furnace, mercury, computer printouts, etc.				X	X	X
- QC sample preparation logbook pages	X	X	X	X	X	X
● MISCELLANEOUS DATA:						
- Original preparation and analysis forms or copies of preparation and analysis logbook pages	X	X	X	X	X	X
- Screening records	X	X	X			X
- All instrument output, including strip charts, from screening activities	X	X	X			X
- Preparation logs raw data	X	X	X	X	X	X
- Percent solids determination log	X	X	X	X	X	X
- Other records (e.g., telephone communication log)	X	X	X	X	X	X

VOA = volatile organic analytes
SVOC = semivolatile organic compounds
PEST = pesticide organic compounds
PCB = polychlorinated biphenyls
CN = cyanide
Other = other parameters
( ) = Form Number, refer to CLP SOW forms if CLP is used

3.5.2.2 On-site Analysis Data Package Deliverables

The QAPP should list the required data package deliverables for all on-site analytical data generated in the field, with required data package turnaround times specified for each analytical group measured on-site.

- **On-site Analytical Screening Data.** The requirements for on-site screening data packages are project-specific. In addition, the usability of on-site screening data depends on the PQOs and the comparability of those data to the definitive confirmatory data generated by an on-site mobile laboratory or off-site laboratory.
- **On-site Analytical Definitive Data.** If on-site analytical data are generated for definitive purposes, then a complete data package should be generated to ensure that data can be properly reviewed.

If complete on-site analysis data packages (i.e., original raw data) are not required deliverables, the QAPP should justify this decision and specify which project data will be kept by the on-site analytical unit, where the data will be stored (the organization's name, address, and exact location in building), and how long it will be stored (the length of time required records must be stored is program-dependent).

Even if complete data packages are not required deliverables in the QAPP, all hard-copy and electronic data and information relevant to the project must be archived in one location by the on-site analytical unit to ensure the data's availability for potential future retrieval and use.

In order to facilitate possible future review, it is strongly recommended that raw data (including electronic media) of all field samples, QC checks and samples, standards, and blanks from all data collection events be archived, if applicable, and be available on request for a minimum of 5 years from the date of generation.

3.5.2.3 Off-site Laboratory Data Package Deliverables

Required data package deliverables for all data generated by off-site laboratories retained to provide analytical services should be itemized in the QAPP, with required data package turnaround times specified for each analytical group.

For all data collection events, a laboratory data package should be provided for each set of samples designated as a sample delivery group (SDG).

A good example of the data package requirements for 18 different analytical methods is found in the EPA Region 9 draft report, *Laboratory Documentation Requirements for Data Validation* (July 1997; 9QA-07-97; available at http://www.epa.gov/region9/qa/pdfs/ldrdv.pdf) Laboratory data package deliverables may include the documents shown in Table 7.

Graded Approach

Depending on the data needs of the project, such as radiological sampling and analysis, information beyond that shown on Table 7 may be required. For other projects, fewer items may be required.

It is strongly recommended that raw data (including electronic media) of all field samples, QC samples, standards, and blanks be archived, if applicable, and be available upon request for 5 years from the date of generation.

Figure 33 (QAPP Worksheet #30) shows what information to include in the Analytical Services table. The organizations or laboratories that will provide the analytical services (for all on-site screening, on-site definitive, and off-site laboratory analytical work, including all prime laboratories, subcontractor laboratories, and backup laboratories) should by identified, grouped by matrix, analytical group, concentration level, and sample locations or ID numbers.

Matrix	Analytical Group	Concentration Level	Sample Location/ ID Number	Analytical SOP	Data Package Turnaround Time	Laboratory/ Organization (Name and Address, Contact Person and Telephone Number)	Backup Laboratory/ Organization (Name and Address, Contact Person and Telephone Number)

Figure 33. Analytical Services (QAPP Worksheet #30)

3.5.3 Data Reporting Formats

The QAPP should discuss procedures and/or SOPs for recording data, including guidelines for recording (e.g., manually, legibly in ink, and initialed and dated by the responsible person) and correcting data (e.g., single line drawn through errors, initialed and dated by the responsible person). The QAPP should include examples of hard-copy data reporting forms and all verification checklists and forms (as an attachment to the QAPP or by referencing the laboratory QA plan or manual). If applicable, the QAPP should discuss specifications for format, content, and computer configuration of electronic data deliverables, and examples of all electronic data deliverable forms should be attached.

3.5.4 Data Handling and Management

The QAPP should describe all computerized and manual procedures that trace the paths of all data from generation to final use and storage, as well as the associated quality checks for error detection that are performed to ensure data integrity. Applicable SOPs may be attached to or referenced in the QAPP. The following data management steps should be addressed:

1. Data Recording

   - Provide examples of data entry forms.
   - Describe internal checks to detect errors such as transcription and calculation errors, the resultant documentation generated, and responsible personnel.
   - Provide examples of all verification checklists and forms.

2. Data Transformations and Data Reduction

   - Provide formulas used in data conversions (e.g., calculation of dry weight field sample concentrations).
   - Describe when and how data conversion procedures are performed, how they are checked, the resultant documentation generated, and responsible personnel.
   - Describe all data manipulations involved in reducing raw data to reportable data, as well as responsible personnel.
   - Provide an example of how raw data are reduced for all manual and automated calculations (e.g., calculation of sample concentrations from peak areas, manual integration procedures).
   - Provide references to specific software documentation for automated data processing.
   - Describe internal checks to detect errors, the resultant documentation generated, and responsible personnel. Provide examples of all verification checklists and forms.
   - Indicate the number of significant figures.

3. Data Transfer and Transmittal

   - Identify electronic data transfer software.
   - Provide examples of electronic data transfer forms.
   - Describe manual data transcription and electronic transmittal procedures, the resultant documentation generated, and responsible personnel.
   - Describe internal checks to detect errors, the resultant documentation generated, and responsible personnel. Provide examples of all verification checklists and forms.

4. Data Analysis

- Identify and describe the data equipment and computer hardware and software that will be used to process, compile, and analyze project data (e.g., the Laboratory Information Management Systems, or LIMS) and secondary data (see Section 2.7).
- Describe in detail the computer models and/or algorithms that will be used for data analysis and justify their use for this project.

5. Data Review

- Describe in detail the computer programs that will be used to review data.
- Describe in detail statistical computer programs that will be used to assess data.
- Indicate the anticipated organization that will be performing data review (see Section 5.0 for details on the data review process).

3.5.5 Data Tracking and Control

The QAPP should describe the procedures for data tracking, storage, archiving, retrieval, and security, including both hard-copy and electronic data and information, and identifying the personnel responsible.

1. Data Tracking

- Describe procedures for tracking data as they are collected, transformed or reduced, transmitted, and analyzed; the resultant documentation generated; and the responsible personnel.

2. Data Storage, Archiving, and Retrieval

- Describe data storage, archiving, and retrieval procedures for all project data, documents, records, and reports. Differentiate between hard-copy and electronic data and information.
- Identify specific project data, documents, records, reports, etc. that will be stored and/or archived. Differentiate between hard-copy and electronic data and information, and between documentation stored at a subcontracted laboratory and documentation archived by the lead organization. If data package deliverables do not include all project data documentation, describe what data (for on-site screening, on-site definitive, and off-site laboratory) will be kept by which laboratory or other organization and the exact physical location for each (i.e., complete laboratory or organization name, address, and specific location in the building).
- Identify the organizations and personnel responsible for storing, archiving, and retrieving specific project documents. Identify responsible document control personnel, including organizational affiliation, telephone, e-mail address, and fax number (see Sections 2.4.1 and 2.4.3).

- Describe where the documents will be stored during the project and where the documents will be archived. Provide exact locations (organization name, complete address, and specific location in building) and timeframes in which documents will be moved from one location to another.
- Indicate when documents will be archived at a final location.

3. Data Security

- Describe procedures for data security.
- Describe procedures for computer security.

4.0 ASSESSMENT AND OVERSIGHT ELEMENTS

This QAPP element group ensures that planned project activities are implemented as described in the QAPP and that reports are provided to apprise management of the project status and any QA issues that arise during implementation. Assessment activities help to ensure that the resultant data quality is adequate for its intended use, and that appropriate responses are in place to address nonconformances and deviations from the QAPP.

Frequently, deviations from the QAPP are identified by project personnel without the benefit of formal, scheduled assessments. This section also addresses those situations and describes the process by which the need for corrective action is documented, reported, and implemented and its effectiveness assessed.

4.1 Assessments and Response Actions

> **Graded Approach**
>
> The PQOs dictate the type, frequency, and extent of the assessments that should be performed.

Appropriately scheduled assessments allow management to implement corrective action measures in a timely manner, thereby minimizing the impact of nonconformance on achieving project quality objectives. Periodic internal and/or external assessments should be conducted throughout the project to ensure that usable data are being generated. In addition, oversight assessments should be performed by the approval authority to identify and correct nonconformances.

The number, frequency, and types of planned assessment activities that will be performed for the project should be identified in the QAPP. Descriptions should include activities for identifying and correcting any problems encountered during the project. The project team should choose assessments that identify activities with the most influence on data quality and provide information about potential problems and mistakes. Sampling error is generally thought to contribute the majority of the measurement error associated with project data, where:

Measurement Error = Sampling Error + Analytical Error

Therefore, all data generation and collection operations should include at least one field sampling technical systems audit (TSA) at the start of field sampling activities so that effective corrective action measures can be implemented to mitigate the extent and impact of identified nonconformances. Both investigative and routine monitoring projects should also include field analytical, on-site laboratory, and off-site laboratory TSAs, as appropriate. An RI/FS with known human health or ecological risks should include comprehensive assessments of field sampling, on-site analytical and off-site laboratory measurement procedures, and proposed remediation technologies, as well as an evaluation of the risk assessment procedures that will be employed.

4.1.1 Planned Assessments

Many different types of assessments are used for evaluating the effectiveness of project activities. The following may be performed by project participants as internal or external assessments, or by the approval authority as oversight audits.

Readiness Review – A systematic, documented review of readiness for the startup or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiating a major phase of work.

Field Sampling TSA – A thorough on-site audit during which sampling design, equipment, instrumentation, supplies, personnel, training, sampling procedures, chain-of-custody, sample handling and tracking, data reporting, data handling and management, data tracking and control, and data review procedures are examined for conformance with the QAPP. At least one field sampling TSA should be performed at the start of field sampling activities.

On-site Analytical TSA – A thorough audit of on-site analytical procedures during which the facility (e.g., mobile lab, trailer), equipment, instrumentation, supplies, personnel, training, analytical methods and procedures, laboratory procedures, sample handling and tracking, data reporting, data handling and management, data tracking and control, and data review procedures are checked for conformance with the QAPP. An on-site analytical TSA can be performed prior to, at the start of, or at any time during field sampling activities. However, at least one on-site analytical TSA should be performed prior to the start of the field sampling activities so that effective corrective action measures can be implemented to mitigate the extent and impact of identified nonconformances.

Off-site Laboratory TSA – A thorough audit of an off-site laboratory during which the facility, equipment, instrumentation, supplies, personnel, training, analytical methods and procedures, laboratory procedures, sample handling and tracking, data reporting, data deliverables, data handling and management, data tracking and control, and data review procedures are checked for conformance with the QAPP. An off-site laboratory TSA can be performed prior to, at the start of, or at any time during field sampling activities. However, it is recommended that at least one off-site laboratory TSA be performed prior to the start of the field sampling activities so that effective corrective action measures can be implemented to mitigate the extent and impact of identified nonconformances.

Split Sampling and Analysis Audit – A comparison study to assess interlaboratory precision and accuracy. The sampler collects one field sample and then physically splits it into two representative sample aliquots. The samples are then sent to different laboratories for analysis. Split samples quantitatively assess the measurement error introduced by the organization's sample shipment and analysis system and must be accompanied by a PT sample to establish the acceptance criteria. Split

sample comparability criteria must be generated prior to sample collection and documented in the QAPP (see Figure 15, Section 2.6.2.5.1).

PT Sample Tracking and Analysis – Statistical analysis of PT sample results, which provides information on routine laboratory performance and the overall accuracy and bias of the analytical method. The QAPP should address the selection of appropriate PT samples. Factors to consider include analyte selection; whether PT samples are single or double blind, native or synthetic matrix, or spiked or natively contaminated or both; multiple matrices and concentrations; total number of PT samples; and analytical methods.

Data Review TSA – A thorough review of the complete data review process, including a review of the sampling and analysis verification, sampling and analysis validation, and data usability assessment steps, to ensure that the process conforms to the procedures specified in the QAPP (for more information, see Section 5.0). The data review TSA may also include an audit of the performance of the data reviewer.

Management Systems Review (MSR) – A review of an organization or organizational subset to determine if the management structure, policies, and procedures are sufficient to ensure that an effective quality system is in place that supports the generation of usable project data. This review is performed against the organization's QMP.

If assessments (audits) are planned, the QAPP should contain the information shown in Figure 34 (QAPP Worksheet #31). If no assessments are planned, the QAPP must contain documentation and justification of that fact.

Assessment Type	Frequency	Internal or External	Organization Performing Assessment	Person(s) Responsible for Performing Assessment, (Title and Organizational Affiliation)	Person(s) Responsible for Responding to Assessment Findings (Title and Organizational Affiliation)	Person(s) Responsible for Identifying and Implementing Corrective Actions (CA) (Title and Organizational Affiliation)	Person(s) Responsible for Monitoring Effectiveness of CA (Title and Organizational Affiliation)

Figure 34. Planned Project Assessments
(QAPP Worksheet #31)

For each planned assessment, the following information should be recorded:

- Assessed organization
- Internal, external or EPA oversight
- Location of assessment
- Dates of assessment

- Assessment team members
- Type of assessment
- Assessment scope
- Documents to be reviewed
- Notification date(s)
- Proposed schedule
- Assessment number
- Contract number

Project-specific questionnaires and audit checklists used for performing assessments should be attached to or referenced in the QAPP. Completed checklists should be attached to the QA management reports, as described in Section 4.2.

Note: Written oversight reports and split sampling results, and subsequent corrective action responses generated by the investigative organization, should be included in QA management and final project reports.

4.1.2 Assessment Findings and Corrective Action Responses

Assessment findings that require corrective action initiate a sequence of events that include documentation of deficiencies, notification of findings, request for corrective action, implementation of corrective action, and follow-up assessment of the corrective action's effectiveness. The QAPP should describe how QAPP deviations and project deficiencies that are identified through the planned project assessments will be handled. For each type of assessment, the QAPP should do the following:

- Describe how deficiencies will be documented and communicated (e.g., verbal debriefing after audit and/or written audit report).
- Describe what type of corrective action responses will be required, and how the responses will be documented.
- Identify individuals who will be notified of audit findings (the name, title, organizational affiliation, position, e-mail address, and telephone and fax numbers of all individuals who should be notified of deficiencies and nonconformances).
- Identify who should receive the corrective action responses.
- Include timeframes allowed for the notification of audit findings, the request for corrective action, the transmittal of corrective action responses, and completion of corrective action.

Figure 35 (QAPP Worksheet #32) provides an example of the Assessment Findings and Corrective Action Responses table.

The content and format of corrective action responses should be tailored to suit the PQOs. In certain situations, a letter documenting specific procedural changes may be a sufficient corrective action response. Appropriate procedural changes can include, but are not limited to, additional staff training, revision of SOPs, and rescheduling of sampling and analytical activities (e.g., to ensure that holding times are met). Corrective actions that must be implemented immediately to ensure that PQOs are met may require that work cease until the corrective actions are implemented and their effectiveness verified.

Assessment Type	Nature of Deficiencies Documentation	Individual(s) Notified of Findings (Name, Title, Org.)	Contact Information	Timeframe of Notification	Nature of Corrective Action Response Documentation	Individual(s) Receiving Corrective Action Response (Name, Title, Org.)	Contact Information	Timeframe for Response
Off-Site Laboratory TSA	*Written audit report*	*Jay Strong QA Officer Ringer Laboratories*	*JS@ringer.com Phone: 755-555-1212 Fax: 755-555-1280*	*5 days after audit*	*Corrective Action Plan*	*Jake Feathers QA Officer Butts Engineering*	*JakeF@buttseng.com 808-555-8000*	*Two weeks after receiving notification*
Split Sampling and Analysis Audit	*Memo*	*Jay Strong Ringer Labs; Jane Black AAA Laboratories*	*JS@ringer.com 755-555-1212; Jane.Black@aaa.com 755-594-0000*	*48 hours after receiving results*	*Letter*	*Jake Feathers QA Officer Butts Engineering*	*Jake@buttseng.com 808-555-8000*	*5 days after receiving notification*

Figure 35. Example Assessment Findings and Corrective Action Responses (QAPP Worksheet #32)

4.2 QA Management Reports

Periodic QA management reports ensure that managers and stakeholders are updated on project status and results of all QA assessments. Efficient communication of project status and problems allows project managers to implement timely and effective corrective actions so data generated can meet PQOs.

The QAPP should describe the content of each QA management report that will be generated for the project, including an evaluation of measurement error as determined from the assessments. Assessment checklists, reports, requests for corrective action letters, and the corrective response letters (refer to Section 4.1.2) should be included as attachments to or referenced in the QA management reports. All QA management reports should be included as attachments to the final project report.

The following issues should be included in the final project report, either as part of the QA management report or in a QA/QC section of the final project report:

- Summary of project QA/QC programs and trainings conducted during the project
- Conformance of project activities to QAPP requirements and procedures
- Status of project and schedule delays

- Deviations from the approved QAPP and approved amendments to the QAPP
- Results and trends of PT samples performed by all laboratories (per analytical group, matrix, and concentration level)
- Description and findings of TSAs and other assessments
- Results of data review activities in terms of amount of usable data generated
- Required corrective actions and effectiveness of corrective action implementation
- Data usability assessments in terms of precision, accuracy, representativeness, completeness, comparability, and sensitivity (refer to Section 5.2)
- Limitations on the use of measurement data generated

Figure 36 (QAPP Worksheet #33) provides an example QA Management Reports table, identifying the frequency and types of reports planned, projected delivery dates, personnel responsible for report preparation, and report recipients.

4.3 Final Project Report

The issues listed above must be addressed in the QA management reports (as attachments to the final project report) or the QA/QC section of the final project report. The final project report must also address additional data quality concerns, including but not limited to the following:

- Narrative and timeline of project activities
- Summary of PQO development
- Reconciliation of project data with PQOs
- Summary of major problems encountered and their resolution
- Data summary, including tables, charts, and graphs with appropriate sample identification or station location numbers, concentration units, percent solids (if applicable), and data quality flags
- Conclusions and recommendations

Type of Report	Frequency (daily, weekly monthly, quarterly, annually, etc.)	Projected Delivery Date(s)	Person(s) Responsible for Report Preparation, Title and Organizational Affiliation	Report Recipients, Title and Organizational Affiliation
Field Sampling Technical Systems Audit Report	*1/At startup of sampling*	*38060*	*Claire Carpenter, Project QA Officer, Chaucer Engineering*	*Dorothy Parker, Project Manager/Geotechnical Engineer & James Keller, Field Sampling Coordinator, Chaucer Engineering; Howard Fast, Poe Recycling Project Manager, Poe Recycling*
Off-site Laboratory Technical Systems Audit Report	*1/Prior to sample receipt*	*38031*	*Claire Carpenter, Project QA Officer, Chaucer Engineering*	*John Grissom, Laboratory QA/QC Manager & Robert Galvani, Laboratory Manager, Austin Labs; Howard Fast, Poe Recycling Project Manager, Poe Recycling; Dorothy Parker, Project Manager/Geotechnical Engineer, Chaucer Engineering*
Data Review Report	*1/After all data generated and reviewed*	*38144*	*Brendan Rivers, Data Validator, BDO Quality Services; Claire Carpenter, Project QA Officer, Chaucer Engineering*	*Dorothy Parker, Project Manager/Geotechnical Engineer, Chaucer Engineering; Howard Fast, Poe Recycling Project Manager, Poe Recycling; Henry Thoreau, EPA Project Manager, EPA-NE*
Final Project Report	*1/After QA Management Reports and Risk Assessment completed*	*38173*	*Dorothy Parker, Project Manager/Geotechnical Engineer, Chaucer Engineering*	*Howard Fast, Poe Recycling Project Manager, Poe Recycling; Henry Thoreau, EPA Project Manager, EPA-NE*

Figure 36. Example QA Management Reports (QAPP Worksheet #33)

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5.0 DATA REVIEW ELEMENTS

Data review is the process which data are examined and evaluated to varying levels of detail and specificity by a variety of personnel who have different responsibilities within the data management process. It includes verification, validation, and usability assessment. This QAPP element group encompasses the data review activities used to ensure that only scientifically sound data that are of known and documented quality and meet project quality objectives (PQOs) are used in making environmental decisions. The approach used for data review of a project must be appropriate to the project requirements.

This section of the Manual defines the steps of data review and describes their implementation. Although data review takes place after the data have been generated, determination of the type of data review that is required to meet PQOs begins during the planning phase of the project. Key questions regarding data review that must be answered during the project planning stage include, but are not limited to, the following:

- What PQOs are necessary to achieve the appropriate level of precision, accuracy, representativeness, comparability, sensitivity, and completeness? (See Section 2.6.1 for a discussion of PQOs.)
- What data review inputs, activities, and outputs will be required for this project? (See Tables 8 and 9 and Section 5.2 for examples.)
- What entities will be responsible for each step of the data review process and what are their relationships to those responsible for the data generation process?
- How will the implementation of the data review process and its results integrate with the overall project decision timeline?
- What is the extent of data review and the availability and appropriate use of streamlining tools? (See Section 5.3.)

Note: Although the data review process outlined in the following sections is portrayed as a sequential process, it may be beneficial (and more cost-effective) for many projects to combine steps. For example, the entity conducting the verification could also conduct the first step of the validation process.

5.1 Overview

This UFP-QAPP Manual defines three distinct evaluative steps that are used to ensure that project data quality needs are met. These data review steps are required for all data collected and used in environmental projects (see the QA/QC Compendium, Part 2B of the UFP-QAPP).

Note: All three data review steps apply to all aspects of data generation, including field sampling and analytical activities.

- **Step I: Verification** (review for completeness) – Confirmation by examination and provision of objective evidence that the specified requirements (sampling and analytical) have been completed.

- **Step II: Validation** – Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. Validation is a sampling and analytical process that includes evaluating compliance with method, procedure, or contract requirements and extends to evaluating against criteria based on the quality objectives developed in the QAPP (e.g., the QAPP measurement performance criteria [MPC]). The purpose of validation is to assess the performance of the sampling and analysis processes to determine the quality of specified data. It is divided into two subparts:

  – Step IIa assesses and documents compliance with methods, procedures, and contracts.
  – Step IIb assesses and documents a comparison with MPC in the QAPP.

- **Step III: Usability Assessment** – Determination of the adequacy of data, based on the results of validation and verification, for the decisions being made. The usability step involves assessing whether the process execution and resulting data meet project quality objectives documented in the QAPP.

Consistency with EPA Documents

Although the requirements in this Manual are consistent with QA/R-5 and QA/G-5, the definitions and scope for data review outlined in this section are different from those in QA/R-5, QA/G-5, and EPA QA/G-8, *Guidance on Environmental Data Verification and Data Validation* (November 2002). The IDQTF purposely expanded the scope to initiate change in the current process and to better ensure that only data of known and documented quality are used to make environmental decisions.

The table below describes the objectives, scope, steps, and output of data review associated with each process term. The table identifies where the scope of the terms used or the steps involved in the process are expansions of current practice.

Table 8. Data Review Process Summary

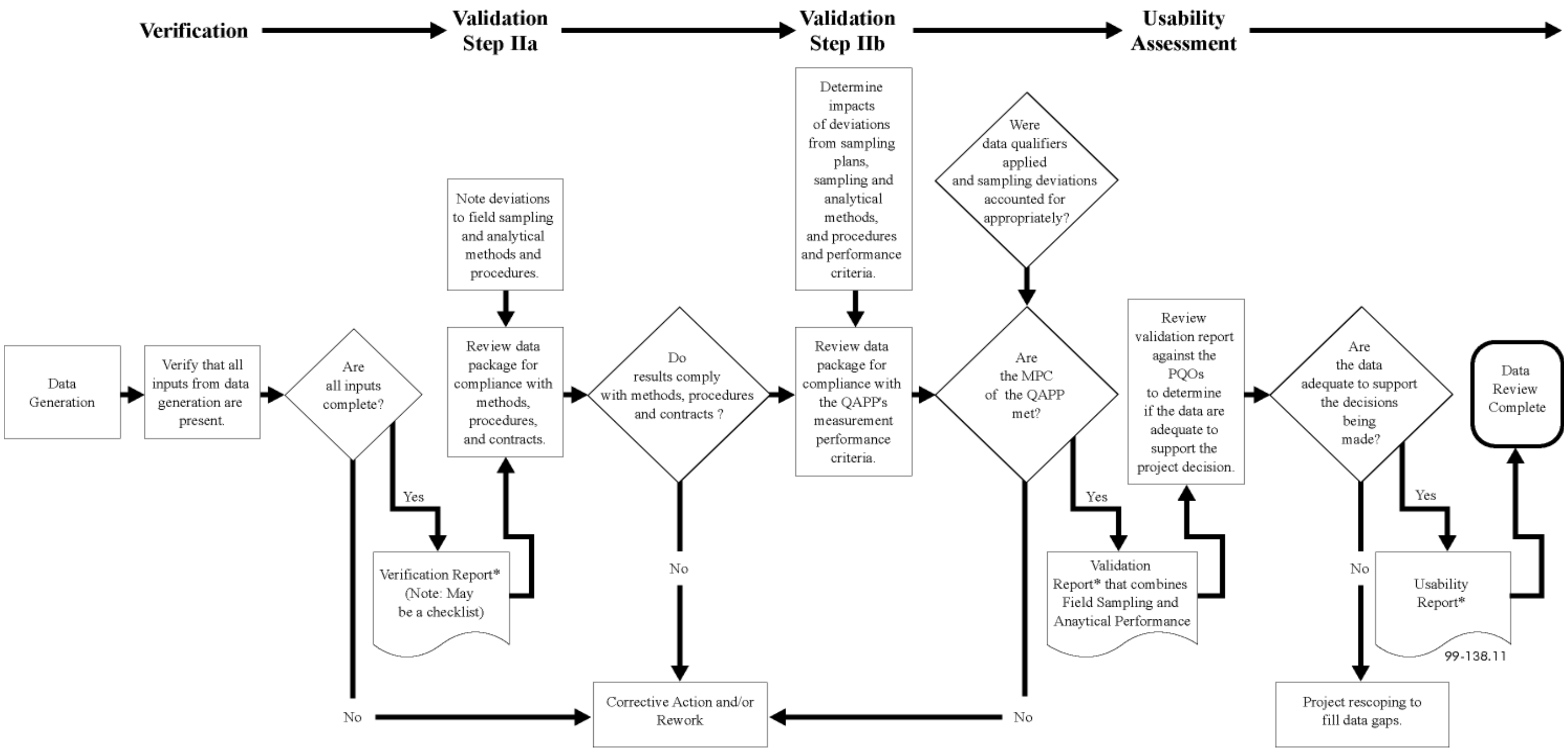
Process Term	Objective	Scope	Data Review Step	Output
Verification	Review to see if data required for the project are available.	– Sampling* – Analysis	I. Completeness check	Verification Report – May be checklist form – Package includes all documentation
Validation	– Assess and document the performance of the field sample collection process. – Assess and document the performance of the analytical process.	– Sampling* – Analysis	IIa. Check compliance with method, procedure, and contract requirements IIb. Compare with measurement performance criteria from the QAPP*	Validation Report – Includes qualified data – May be part of other report such as RI/FS
Usability Assessment*	Assess and document usability to meet project quality objectives.	- Sampling - Analysis	III. Assess usability of data by considering project quality objectives and the decision to be made*	Usability Report – May be part of other report such as RI/FS

*The scope of the term or the step involved is an expansion of current practice.

The expansion of scope of terms and steps from current data review practice encompasses the following:

- The terms *verification* and *validation* apply to field sampling activities, as well as to the analytical component of data generation.
- Validation assesses not only compliance with method, procedure, and contract requirements, but also compliance with QAPP-specific requirements.
- Usability assessments are a minimum requirement for all environmental project phases and data uses. This is the final step of data review: assessing whether the data are suitable as a basis for the decision.

Figure 37 outlines the data review process described in this UFP-QAPP Manual. Each step of the process is critical to the overall assessment of data quality and each step builds on the outcome of the previous step. The level of data review (types and amount of data reviewed) should be appropriate to the PQOs. Streamlining data review (validation in particular) is an option to consider to potentially eliminate some validation requirements, if allowed by the project's data quality needs (see Section 5.3).



Notes:
* Does not have to be a separate report - may be part of RI/FS or other document.
Although the steps shown here are presented in a sequential manner, certain steps in the data review process may be performed simultaneously.

Figure 37. Data Review Process

In order to perform the data review steps described above, reported analytical data must be supported by complete data packages, as defined in the QAPP (see Table 7, Section 3.5.2). Data packages include sample receipt and tracking information, chain-of-custody records, tabulated data summary forms, and raw analytical data for all field samples, standards, QC samples, and all other project-specific documents that are generated. If relevant raw data or sample information are not available or adequate to document data quality, then data review cannot be performed, and resampling or reanalysis must be considered. Secondary data should also be evaluated during data review, if available.

5.2 Data Review Steps

This section of the Manual describes what data review information must be included in the QAPP and presents procedures for implementing each of the three data review steps: verification (step I), validation (steps IIa and IIb), and usability assessment (step III). Example activities are provided to clarify the types of procedures that may be performed.

Table 9 lists example inputs for data review and identifies the step of the data review process to which each input applies. These are only examples and are not intended to be either a minimum or comprehensive list of inputs.

5.2.1 Step I:Verification

Verification is a completeness check that is performed before the data review process continues in order to determine whether the required information (the complete data package) is available for further review. It involves a review of all data inputs to ensure that they are present. The question answered by this step is: Are the inputs present? (Yes or no). Table 9 provides examples of the inputs for conducting the completeness check. Although this step is not designed for use in qualitative review (e.g., a compliance check that takes place during step IIa of the validation process), it is essential for ensuring the availability of sufficient information for subsequent steps of the data review process.

Table 9. Example Inputs to Data Review Process

	Item	Step I Verification	Step IIa Compliance	Step IIb Comparison	Step III Usability
	Planning Documents				
1	Evidence of required approval of plan (QAPP)	X			Uses outputs from previous steps
2	Identification of personnel (those involved in the project and those conducting verification steps)	X			
3	Laboratory name	X			
4	Methods (sampling and analysis)	X	X		
5	Performance requirements (including QC criteria) for all inputs	X	X	X	
6	Project quality objectives	X		X	
7	Reporting forms	X	X		
8	Sampling plans, location, maps, grids, and sample ID numbers	X	X		
9	Site identification	X			
10	SOPs (sampling and analytical)	X	X		
11	Staff training and certification	X			
12	List of project-specific analytes	X	X		
	Analytical Data Package				
13	Case narrative	X	X	X	Uses outputs from previous steps
14	Internal laboratory chain of custody	X	X		
15	Sample condition upon receipt, and storage records	X	X		
16	Sample chronology (time of receipt, extraction, and analysis)	X	X		
17	Identification of QC samples (sampling or lab, temporal, and spatial)	X	X		
18	Associated (batch or periodic) PT sample results	X	X	X	
19	Communication logs	X	X		
20	Copies of laboratory notebook, records, prep sheets	X	X		
21	Corrective action reports	X	X		
22	Definitions of laboratory qualifiers	X	X	X	
23	Documentation of corrective action results	X	X	X	
24	Documentation of individual QC results (e.g., spike, duplicate, LCS)	X	X	X	
25	Documentation of laboratory method deviations	X	X	X	
26	Electronic data deliverables	X	X		
27	Instrument calibration reports	X	X	X	
28	Laboratory name	X	X		
29	Laboratory sample identification numbers	X	X		
30	QC sample raw data	X	X	X	
31	QC summary report	X	X	X	
32	Raw data	X	X	X	
33	Reporting forms, completed with actual results	X	X	X	
34	Signatures for laboratory sign-off (e.g., laboratory QA manager)	X	X		

Table 9. Example Inputs to Data Review Process (continued)

	Item	Step I Verification	Step IIa Compliance	Step IIb Comparison	Step III Usability
35	Standards traceability records (to trace standard source from NIST, for example)	X	X	X	
	Sampling Documents				
36	Chain of custody	X	X		
37	Communication logs	X	X		
38	Corrective action reports	X	X	X	
39	Documentation of corrective action results	X	X	X	
40	Documentation of deviation from methods	X	X	X	
41	Documentation of internal QA review	X	X	X	
42	Electronic data deliverables	X	X		
43	Identification of QC samples	X	X	X	
44	Meteorological data from field (e.g., wind, temperature)	X	X	X	
45	Sampling instrument decontamination records	X	X		
46	Sampling instrument calibration logs	X	X		
47	Sampling location and plan	X	X	X	
48	Sampling notes and drilling logs	X	X	X	
49	Sampling report (from field team leader to project manager describing sampling activities)	X	X	X	
	External Reports				
50	External audit report	X	X	X	Uses outputs from previous steps
51	External PT sample results	X	X		
52	Laboratory assessment	X	X		
53	Laboratory QA plan	X	X		
54	MDL study information	X	X	X	
55	NELAP accreditation	X	X		

The QAPP planning process must establish verification procedures, which should be documented in the QAPP to ensure that data are evaluated properly, completely, and consistently for use in meeting PQOs. The procedures should address the following:

- The process that will be used to verify sample collection, handling, field analysis, and analytical laboratory project data.
- The procedures and criteria that will be used to verify data information operations. These operations include, but are not limited to, the electronic and/or manual transfer, entry, use, and reporting of data for computer models, algorithms, and databases; correlation studies between variables; data plotting and so forth.

Figure 38 (QAPP Worksheet #34) provides an example Verification (Step I) Process table that can be used to present the process that will be followed to verify project data. Verification inputs include

items such as those listed in Table 9. The description should detail how each item will be verified, when the activity will occur, and what documentation is necessary. *Internal* or *external* is in relation to the data generator. The resulting tables will describe the following:

- How sample collection, handling, and analysis procedures will be verified.
- How verification of field sampling, handling, and analysis activities will be documented (e.g., QC signatures in field logs, QC checklist, etc.).
- Which sampling, handling, on-site analytical, and off-site laboratory data will be verified internally at the data generator level.
- The end product of laboratory verification (e.g., laboratory-qualified data).
- Which sampling, on-site analytical, and off-site laboratory data will be verified by entities external to the data generator.

Verification Input	Description	Internal/ External	Responsible for Verification (Name, Organization)
Chain of custody	*Chain-of-custody forms will be reviewed internally upon their completion and verified against the packed sample coolers they represent. When everything checks out, the shipper's signature on the chain-of-custody form will be initialed by the reviewer, a copy of the form will be retained in the site file, and the original and remaining copies will be taped inside the cooler for shipment. See SOPs for further details.*	*I*	*Cole Lector* *Jewel Engineering*
Analytical data package	*All analytical data packages will be verified internally by the laboratory performing the work for completeness prior to submittal. The laboratory shall complete the appropriate form documenting the organization and complete contents of each data package.*	*I*	*Jasper Sanquin* *Emerald Environmental Lab*
QC summary report	*A summary of all QC sample results will be verified for completeness by the prime contractor upon receipt of data packages from the laboratory.*	*E*	*Tammy Finsk* *Whole World Consulting, Inc.*

Figure 38. Example Verification (Step I) Process (QAPP Worksheet #34)

5.2.2 Step II: Validation

The QAPP planning process must establish validation procedures and criteria. Project-specific validation procedures are developed to identify and qualify data that do not meet the measurement performance criteria as established in Section 2.6.2. Validation procedures and criteria are documented in the QAPP to ensure that data are evaluated properly, completely, and consistently

for use in meeting PQOs. Validation guidance and documents may be attached to or referenced in the QAPP and should address the following:

- The process that will be used to validate sample collection, handling, field analysis, and analytical laboratory project data (example activities are listed in Section 5.2.2.1 and 5.2.2.2).
- The specific validation process that will be used for each analytical group, matrix, and concentration level.
- The procedures and criteria used to validate data information operations, which may include, but are not limited to, the electronic or manual transfer, entry, use, and reporting of data for computer models, algorithms, and databases; correlation studies between variables; data plotting and so forth.

Figure 39 (QAPP Worksheet #35) shows what information to include in the Validation Process (Steps IIa and IIb) table that can be used to present the process that will be followed to validate project data.

Validation inputs include items such as those listed in Table 9. The description should detail how each item will be validated, when the activity will occur, and what documentation is necessary. The resulting tables will describe the following:

- How sample collection, handling, and analysis procedures will be validated against the measurement performance criteria specified in Section 2.6.2.
- How validation of field sampling, handling, and analysis activities will be documented (e.g., QC signatures in field logs, QC checklist, etc.).
- Which sampling, on-site analytical, and off-site laboratory data will be validated.
- The evaluative procedures used in validation to assess overall measurement error associated with the project, including the data quality indicators (DQIs) described in Section 5.2.3.2.
- The individual, identified by title and organizational affiliation, who is ultimately responsible for data validation. This is the person (lead chemist, project chemist, etc.) who will sign the project validation reports.

Step IIa/IIb	Validation Input	Description	Responsible for Validation (Name, Organization)

Figure 39. Validation (Steps IIa and IIb) Process (QAPP Worksheet #35)

In addition, the QAPP should identify the matrices, analytical groups, and concentration levels that each entity performing validation will be responsible for, as well as the criteria that will be used to validate those data. Figure 40 (QAPP Worksheet #36) provides an example of the Validation Summary (Steps IIa and IIb) table. In a table, the validation criteria column may reference an outside

guidance document (e.g., CLP Functional Guidelines) or different section of the QAPP. The title and affiliation of the person who will perform the validation should be included for each entry, since this may be different from the person ultimately responsible for the entire validation.

Step IIa/IIb	Matrix	Analytical Group	Concentration Level	Validation Criteria	Validator (title and organizational affiliation)
IIa	*Soil*	*VOA*	*Low*	*SW-846 Method 8260B, SOPs*	*Tom Lee, Chemist, Best Review Company*
IIa	*GW*	*Metal*	*Low/Medium*	*SW-846 Method 6010B, SOPs*	*Tom Lee, Chemist, Best Review Company*
IIb	*Soil*	*VOA*	*Low*	*See QAPP section 2.7*	*Paula Simpson, Sr. Chemist, Whatayuk Consulting*

**Figure 40. Example Validation Summary (Steps IIa and IIb)
(QAPP Worksheet #36**

Note: Sources of sampling and analytical error should be identified and corrected as soon as possible after sample collection activities have begun. Incorporating an ongoing usability assessment process throughout the project, rather than just as a final step, will facilitate the early detection and correction of problems, thereby ensuring that PQOs are met.

Streamlining Validation

Some requirements for validation may be eliminated depending on project-specific data needs. Section 5.3 addresses the criteria for streamlining and amounts and types of data to be streamlined.

5.2.2.1 Step IIa Validation Activities

The examples listed in Table 10 are of specific activities that may occur during an environmental project under step IIa of the validation process (compliance with methods, procedures, and contracts) for both sampling and analytical data. Although these activities are organized separately, they may be performed at the same time and/or by the same people as step I and step IIb activities.

**Table 10. Step IIa Validation Activities
(Compliance with Methods, Procedures, and Contracts)**

	Activity
Data Deliverables and QAPP	Ensure that all required information on sampling and analysis from step I was provided (including planning documents).
Analytes	Ensure that required lists of analytes were reported as specified in governing documents (i.e., method, procedure, or contract).
Chain-of-Custody	Examine the traceability of the data from time of sample collection until reporting of data. Examine chain-of-custody records against contract, method, or procedural requirements.
Holding Times	Identify holding time criteria, and either confirm that they were met or document any deviations. Ensure that samples were analyzed within holding times specified in method, procedure, or contract requirements. If holding times were not met, confirm that deviations were documented, that appropriate notifications were made (consistent with procedural requirements), and that approval to proceed was received prior to analysis.
Sample Handling	Ensure that required sample handling, receipt, and storage procedures were followed, and that any deviations were documented.
Sampling Methods and Procedures	Establish that required sampling methods were used and that any deviations were noted. Ensure that the sampling procedures and field measurements met performance criteria and that any deviations were documented.
Field Transcription	Authenticate transcription accuracy of sampling data (i.e., from field notebook to reports).
Analytical Methods and Procedures	Establish that required analytical methods (off-site laboratory and on-site analytical) were used and that any deviations were noted. Ensure that the QC samples met performance criteria and that any deviations were documented.
Data Qualifiers	Determine that the laboratory data qualifiers were defined and applied as specified in methods, procedures, or contracts.
Laboratory Transcription	Authenticate accuracy of the transcription of analytical data (i.e., laboratory notebook to reporting form, or instrument to LIMS).
Proficiency Testing	Confirm acceptance of PT sample results against performance requirements as specified in methods, procedures, or contracts.
Standards	Determine that standards are traceable and meet contract, method, or procedural requirements.
Communication	Establish that required communication procedures were followed by field or laboratory personnel.

Table 10. Step IIa Validation Activities (continued)

	Activity
Audits	Review field and laboratory audit reports and accreditation and certification records for the laboratory's performance on specific methods.
Step IIa Validation Report	Summarize deviations from methods, procedures, or contracts. Include qualified data and explanation of all data qualifiers.

5.2.2.2 Step IIb Validation Activities

The examples listed in Table 11 are of specific activities that may occur during an environmental project under step IIb of the validation process (comparison with measurement performance criteria in the QAPP) for both sampling and analytical data. These activities require that the validators have a complete copy of the QAPP, and they often involve all or parts of the project team. Some of the activities listed for step IIa have a QAPP-specific review element and are therefore also listed as activities under step IIb.

Table 11. Step IIb Validation Activities
(Comparison with Measurement Performance Criteria in the QAPP)

	Activity
Data Deliverables and QAPP	Ensure that the data report from step IIa was provided.
Deviations	Determine the impacts of any deviations from sampling or analytical methods and SOPs. For example, confirm that the methods given in the QAPP were used and, if they were not, determine if data still meet MPCs. Consider the effectiveness and appropriateness of any corrective action.
Sampling Plan	Determine whether the sampling plan was executed as specified (i.e., the number, location, and type of field samples were collected and analyzed as specified in the QAPP).
Sampling Procedures	Evaluate whether sampling procedures were followed with respect to equipment and proper sampling support (e.g., techniques, equipment, decontamination, volume, temperature, preservatives, etc.).
Co-located Field Duplicates	Compare results of collocated field duplicates with criteria established in the QAPP.

Table 11. Step IIb Validation Activities (continued)

	Activity
Project Quantitation Limits	Determine that quantitation limits were achieved, as outlined in the QAPP and that the laboratory successfully analyzed a standard at the QL.
Confirmatory Analyses	Evaluate agreement of laboratory results.
Performance Criteria	Evaluate QC data against project-specific performance criteria in the QAPP (i.e., evaluate quality parameters beyond those outlined in the methods).
Data Qualifiers	Determine that the data qualifiers applied in step IIa were those specified in the QAPP and that any deviations from specifications were justified.
Step IIb Validation Report	Summarize outcome of comparison of data to MPC in the QAPP. Include qualified data and explanation of all data qualifiers.

5.2.3 Step III: Usability Assessment

A usability assessment considers whether data meet project quality objectives as they relate to the decision to be made, and evaluates whether data are suitable for making that decision. All types of data (e.g., sampling, on-site analytical, off-site laboratory) are relevant to the usability assessment. The usability assessment is the final step of data review and can be performed only on data of known and documented quality (i.e., verified and validated data).

To accomplish this step of data review, the project team should do the following:

- Summarize the usability assessment process and all usability assessment procedures, including interim steps and any statistics, equations, and computer algorithms that will be used to assess data (example activities are listed in Section 5.2.3.2).
- Describe the documentation that will be generated during usability assessment.
- Identify the personnel (by title and organizational affiliation) responsible for performing the usability assessment.
- Describe how usability assessment results will be presented so that they identify trends, relationships (correlations), and anomalies.
- Describe the evaluative procedures used to assess overall measurement error associated with the project and include the DQIs described in Section 5.2.3.1.

QAPP Worksheet #37, Usability Assessment, may be used for this purpose.

5.2.3.1 Data Limitations and Actions from Usability Assessment

The following data quality indicators (precision, accuracy/bias, representativeness, comparability, completeness, and sensitivity) are important components of validation and usability assessment. A description of how they should be incorporated into the usability report is found under each parameter heading. Further discussion of the importance of these parameters as they relate to specific QC samples can be found in Sections 2.6.2 and 3.4 of this UFP-QAPP Manual, and Section 2.2 of the QA/QC Compendium.

When project-required measurement performance criteria are not achieved and project data are not usable to adequately address environmental questions (i.e., to determine if regulatory or technical action limits have been exceeded) or to support project decision-making, then the usability report should address how this problem will be resolved and discuss the potential need for resampling.

5.2.3.1.1 Precision

Precision is the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision is usually expressed as standard deviation, variance, percent difference, or range, in either absolute or relative terms. Examples of QC measures for precision include field duplicates, laboratory duplicates, matrix spike duplicates, analytical replicates, and surrogates.

In order to meet the needs of the data users, project data must meet the measurement performance criteria for precision specified in the QAPP (see Section 2.6.2.1). Section 2.2.2 and Table A-1 of the QA/QC Compendium identify QC samples required for projects in the CERCLA process that contribute to the measurement of precision.

Poor overall precision may be the result of one or more of the following: field instrument variation, analytical measurement variation, poor sampling technique, sample transport problems, or spatial variation (heterogeneous sample matrices). To identify the cause of imprecision, the field sampling design rationale and sampling techniques should be evaluated by the reviewer, and both field and analytical duplicate/replicate sample results should be reviewed. If poor precision is indicated in both the field and analytical duplicates/replicates, then the laboratory may be the source of error. If poor precision is limited to the field duplicate/replicate results, then the sampling technique, field instrument variation, sample transport, and/or spatial variability may be the source of error.

If data validation reports indicate that analytical imprecision exists for a particular data set or sample delivery group (SDG), then the impact of that imprecision on usability must be discussed in the usability report.

Usability Report

The usability report should discuss and compare overall field duplicate precision data from multiple data sets collected for the project for each matrix, analytical group, and concentration level. Usability reports should describe the limitations on the use of project data when overall precision is poor or when poor precision is limited to a specific sampling or laboratory (analytical) group, data set or SDG, matrix, analytical group, or concentration level.

5.2.3.1.2 Accuracy/Bias

Accuracy is the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias), that are due to sampling and analytical operations. Examples of QC measures for accuracy include PT samples, matrix spikes, laboratory control samples (LCSs), and equipment blanks.

In order to meet the needs of the data users, project data must meet the measurement performance criteria for accuracy/bias specified in the QAPP (see Section 2.6.2.2). Section 2.2.2 and Tables A-2 and A-3 of the QA/QC Compendium identify QC samples required for projects in the CERCLA process that contribute to the measurement of accuracy.

Usability Report

The usability report should:

- Discuss and compare overall contamination and accuracy/bias data from multiple data sets collected for the project for each matrix, analytical group, and concentration level.
- Describe the limitations on the use of project data if extensive contamination and/or inaccuracy or bias exist, or when inaccuracy is limited to a specific sampling or laboratory group, data set or SDG, matrix, analytical group, or concentration level.
- Identify qualitative and/or quantitative bias trends in multiple proficiency testing (PT) sample results for each matrix, analytical group, and concentration level.
- Discuss the impact of any qualitative and quantitative trends in bias on the sample data.

Any PT samples that have false positive or false negative results should be reported, and the impact on usability should be discussed in the usability report.

5.2.3.1.3 Representativeness

Representativeness is the measure of the degree to which data accurately and precisely represent a characteristic of a population, a parameter variation at a sampling point, a process condition, or an environmental condition. In order to meet the needs of the data users, project data must meet the measurement performance criteria for sample representativeness specified in the QAPP (see Section 2.6.2.4).

The QAPP should discuss how the QA/QC activities (review of sampling design and SOPs, field sampling TSAs, split sampling and analysis audits, etc.) and QC sample data will be reviewed to assess sample representativeness. If field duplicate precision checks indicate potential spatial variability, additional scoping meetings and subsequent resampling may be needed in order to collect data that are more representative of a nonhomogeneous site.

Usability Report

The usability report should discuss and compare overall sample representativeness for each matrix, analytical group, and concentration level. Usability reports should describe the limitations on the use of project data when overall nonrepresentative sampling has occurred, or when nonrepresentative sampling is limited to a specific sampling, group, data set or SDG, matrix, analytical group, or concentration level.

5.2.3.1.4 Comparability

Comparability is the degree to which different methods, data sets, and decisions agree or can be represented as similar. Comparability describes the confidence (expressed qualitatively or quantitatively) that two data sets can contribute to a common analysis and interpolation. In order to meet the needs of the data users, project data must meet the measurement performance criteria for comparability specified in the QAPP (see Section 2.6.2.5).

The QAPP should include methods and formulas for assessing data comparability for each matrix, analytical group, and concentration level. Different situations require different assessments of comparability, as in the following:

- If two or more sampling procedures or sampling teams will be used to collect samples, describe how comparability will be assessed for each matrix, analytical group, and concentration level.
- If two or more analytical methods or SOPs will be used to analyze samples of the same matrix and concentration level for the same analytical group, describe how comparability will be assessed between the two data sets.
- If split samples are analyzed, document the specific method and percent difference formula that will be used to assess split sample comparability for individual data points (refer to Section 2.6.2.5.1). To document overall comparability, describe the procedures used to perform overall

assessment of oversight split sampling comparability and include mathematical and statistical formulas for evaluating oversight split sampling data comparability. Section 2.2.2 of the QA/QC Compendium recommends that, for proper evaluation of results, split samples should be used only when accompanied by a batch-specific PT sample.

- If screening data will be confirmed by definitive methods, document the specific method and percent difference formula that will be used to assess comparability for individual data points (refer to Section 2.6.2.5.2). To document overall comparability, describe the procedures used to perform overall assessment of comparability and include mathematical and statistical formulas for evaluating screening and confirmatory data comparability.
- If the project is long-term monitoring, project data should be compared with previously generated data to ascertain the possibility of false positives and false negatives, and positive and negative trends in bias. Data comparability is extremely important in these situations. Anomalies detected in the data may reflect a changing environment or indicate sampling and/or analytical error. Comparability criteria should be established to evaluate these data sets to identify outliers and the need for resampling as warranted.

Usability Report

The usability report should:

- Discuss and compare overall comparability between multiple data sets collected for the project for each matrix, analytical group, and concentration level.
- Describe the limitations on the use of project data when project-required data comparability is not achieved for the overall project or when comparability is limited to a specific sampling or laboratory group, data set or SDG, matrix, analytical group, or concentration level.
- Document the failure to meet screening/confirmatory comparability criteria and discuss the impact on usability.
- Document the failure to meet split sampling comparability criteria and discuss the impact on usability.
- If data are not usable to adequately address environmental questions or support project decision-making, address how this problem will be resolved and discuss the potential need for resampling.
- If long-term monitoring data are not comparable, address whether the data indicate a changing environment or are a result of sampling or analytical error.

5.2.3.1.5 Sensitivity and Quantitation Limits

Sensitivity is the capability of a test method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. Examples of QC measures for determining sensitivity include laboratory fortified blanks, a method detection limit study, and calibration standards at the quantitation limit (QL).

In order to meet the needs of the data users, project data must meet the measurement performance criteria for sensitivity and project QLs specified in the QAPP (see Section 2.6.2.3). Section 2.2.2

and Table A-4 of the QA/QC Compendium identify QC samples required for projects in the CERCLA process that contribute to the measurement of sensitivity.

The QAPP should include the following:

- Methods and formulas for calculating analytical sensitivity that ensure QLs are achieved (e.g., percent recovery of laboratory fortified blank compounds)
- Procedures for calculating MDLs, QLs, and SQLs (refer to Figure 14 in Section 2.6.2.3)
- Procedures for evaluating low-point calibration standards run at the QL

Usability Report

The usability report should:

- Discuss and compare overall sensitivity and QLs from multiple data sets collected for the project for each matrix, analytical group, and concentration level.
- Discuss the impact of that lack of sensitivity or higher QLs on data usability, if validation reports indicate that sensitivity or QLs were not achieved .
- Describe the limitations on the use of project data if project-required sensitivity and QLs are not achieved for all project data, or when sensitivity is limited to a specific sampling or laboratory group, data set or SDG, matrix, analytical group, or concentration level.

5.2.3.1.6 Completeness

Completeness is a measure of the amount of valid data obtained from a measurement system compared with the amount that was expected to be obtained under correct, normal circumstances.

In order to meet the needs of the data users, project data must meet the measurement performance criteria for data completeness specified in the QAPP (see Section 2.6.2.6).

The QAPP should:

- Include the methods and formulas for calculating data completeness.
- Describe how the amount of valid data will be determined as a percentage of the number of valid measurements that are specified in the QAPP for each matrix, analytical group, and concentration level.
- Describe how critical data will be assessed for completeness when certain sample locations or analytes and matrices are more critical than others in making project decisions.

Usability Report

The usability report should:

- Discuss and compare overall completeness of multiple data sets collected for the project for each matrix, analytical group, and concentration level.
- Describe the limitations on the use of project data if project-required completeness is not achieved for the overall project, or when completeness is limited to a specific sampling or laboratory group, data set or SDG, matrix, analytical group, or concentration level.

5.2.3.2 Activities

The entire project team should reconvene to perform the usability assessment to ensure that the PQOs are understood and the full scope is considered. The items listed in Table 12 are examples of specific items that should be considered during an environmental project under the usability assessment.

Table 12. Considerations for Usability Assessment

Item	Assessment Activity
Data Deliverables and QAPP	Ensure that all necessary information was provided, including but not limited to validation results.
Deviations	Determine the impact of deviations on the usability of data.
Sampling Locations, Deviation	Determine if alterations to sample locations continue to satisfy the project objectives.
Chain-of-Custody, Deviation	Establish that any problems with documentation or custody procedures do not prevent the data from being used for the intended purpose.
Holding Times, Deviation	Determine the acceptability of data where holding times were exceeded.
Damaged Samples, Deviation	Determine whether the data from damaged samples are usable. If the data cannot be used, determine whether resampling is necessary.
PT Sample Results, Deviation	Determine the implications of any unacceptable analytes (as identified by the PT sample results) on the usability of the analytical results. Describe any limitations on the data.

Table 12. Considerations For Usability Assessment (continued)

Item	Assessment Activity
SOPs and Methods, Deviation	Evaluate the impact of deviations from SOPs and specified methods on data quality.
QC Samples	Evaluate the implications of unacceptable QC sample results on the data usability for the associated samples. For example, consider the effects of observed blank contamination.
Matrix	Evaluate matrix effects (interference or bias).
Meteorological Data and Site Conditions	Evaluate the possible effects of meteorological (e.g., wind, rain, temperature) and site conditions on sample results. Review field reports to identify whether any unusual conditions were present and how the sampling plan was executed.
Comparability	Ensure that results from different data collection activities achieve an acceptable level of agreement.
Completeness	Evaluate the impact of missing information. Ensure that enough information was obtained for the data to be usable (completeness as defined in PQOs documented in the QAPP).
Background	Determine if background levels have been adequately established (if appropriate).
Critical Samples	Establish that critical samples and critical target analytes/COCs, as defined in the QAPP, were collected and analyzed. Determine if the results meet criteria specified in the QAPP.
Data Restrictions	Describe the exact process for handling data that do not meet PQOs (i.e., when measurement performance criteria are not met). Depending on how those data will be used, specify the restrictions on use of those data for environmental decision-making.
Usability Decision	Determine if the data can be used to make a specific decision considering the implications of all deviations and corrective actions.
Usability Report	Discuss and compare overall precision, accuracy/bias, representativeness, comparability, completeness, and sensitivity for each matrix, analytical group, and concentration level. Describe limitations on the use of project data if criteria for data quality indicators are not met.

5.3 Streamlining Data Review

Streamlining data review refers to a process of eliminating some requirements for validation (steps IIa and IIb) that are deemed no longer necessary to preserve data integrity. Streamlining data review

is meant to reduce time and costs while still confirming the quality of the data. Thus, any streamlining option should recognize that:

- The types and amounts of data reviewed should be sufficient to develop a clear understanding of the quality of the data.
- The practice of reviewing a subset of data (or a data indicator such as a successful PT sample) as a substitute for reviewing all data should be reevaluated if problems are detected that call into question the quality of the data set.

Streamlining data review occurs when efficiencies are created in the data review process by the following actions:

- Looking at a subset of data that is representative of a larger universe.
- Examining the data in an alternative manner (e.g., through the use of batch-specific PT samples).

Different EPA Regions, DoD components, and DOE facilities have negotiated a variety of streamlining options with different projects. The decision as to the nature and type of streamlining to be conducted is determined by the project team on a site-by-site or facility-by-facility basis and must be documented in the QAPP. The QAPP should also contain decision criteria that allow for revision of the initial streamlining plan. For example, decision criteria contained in the QAPP could specify that if problems are identified in the investigation, then streamlining cannot occur. Other factors may also lead to a revision of the initial streamlining decision, such as intense political interest and concern on the part of the community. The QAPP should contain a statement that prohibits streamlining when conditions are not optimal.

Applicability of streamlining options is addressed in three ways: data review steps for which streamlining may be applicable, criteria for considering the streamlining of data review, and level and type of streamlining to be applied. Each of these is addressed below.

5.3.1 Data Review Steps To Be Streamlined

Use of streamlining of data review steps is negotiated on a project-specific basis, in accordance with the criteria outlined below, and is documented in the project-specific QAPP. The decision of whether to streamline data review or not occurs during a step IIa of the validation process (compliance with method, procedural, and contractual requirements) and subsequent steps that rely on outputs from step IIa. The level of streamlining in the data review steps (IIa, IIb, and III) is evaluated on a project-specific basis.

Verification. Step I (verification) is not subject to streamlining. This step is a completeness check of all of the sampling and analytical data associated with the project. It is conducted by the

environmental laboratory (for analytical data) and by the prime contractor (for both sample collection and analytical data). It may be conducted externally.

Validation. Step IIa (validation) may be streamlined based on criteria described in Section 5.3.2. The amount of streamlining and the type of information to be streamlined is negotiated on a project-by-project basis that takes into account the cost savings of streamlining analytical data validation and review, while maintaining sufficient representativeness to ensure quality. Validation step IIb (consistency with QAPP-specific requirements) can be streamlined to the same degree as step IIa, since it relies on the outputs of step IIa.

Usability Assessment. Step III (usability assessment) can be streamlined only to the degree that step IIa is streamlined, given that usability relies on outputs from previous steps.

5.3.2 Criteria for Streamlining Data Review

For each project, the following criteria are used to qualitatively evaluate the extent to which a streamlined data review process for validation steps IIa and IIb is appropriate:

- Level of risk associated with the target analytes/COCs at the site (not always known in the planning stage).
- Cost and schedule demands of the overall project (could drive a decision to implement streamlining that may speed up the project and reduce costs).
- The specific decisions for which the data will be used (e.g., risk assessment or determination of whether further investigation is required).
- Complexity of analysis (more streamlining may be acceptable for simple analyses; less streamlining may be appropriate for highly complex analyses).
- Ability to identify critical (most significant) samples and focus data review on those samples.
- Political attention to project (could drive more streamlining, in the case of time pressures, or less streamlining, in the case of potentially elevated risks).
- Results of project-specific audits suggesting that data quality problems exist or that contractors are performing high-quality work.
- Sampling events that include recurring samples (i.e., monthly or quarterly long-term monitoring of the same chemicals could lead to streamlined validation for these events).
- Proximity of results to action levels. For example, analytical levels that are close to action levels may require a higher level of confidence (and a greater amount of validation) than levels that are considerably above action levels and for which validation is not likely to show a difference in the presence or absence of risk.
- Availability of successfully performed batch-specific PT samples. The PT sample should be of a similar matrix, contaminant makeup, and concentration as the environmental samples being tested, and quantitative acceptance criteria should be established. Batch-specific PT samples may be used to streamline the analytical portion of validation only. Section 2.2.3 of the QA/QC

Compendium summarizes the issues surrounding a requirement for batch-specific PT samples, and Section 2.3.3.2 describes the circumstances that may allow their use as a tool to streamline validation.

5.3.3 Amounts and Types of Data Appropriate for Streamlining

The amounts and types of data to be streamlined (for steps IIa and IIb), as well as the nature of the streamlining activity, will be determined by site-specific circumstances. Some examples of streamlining options are presented below:

- Only a specific percentage of all data sets will be validated (e.g., 10 percent), unless a problem is identified.
- Only a specific percentage of all data sets will be validated, but all critical samples, as identified in the QAPP, will undergo full data review.
- Only a specific percentage of all data sets will be validated, but that validation will include recalculation of raw data.
- All data will be validated, but only a percentage of raw data will be reviewed and recalculated.
- Successful batch-specific PT samples may substitute for validation of all or some of the analytical data.

> **Note:** The term *validation* has traditionally applied to analytical data. As used here, the term applies both to data from field sampling and analytical activities. Since the environmental community has more experience with validation for analytical data, it is easier to identify some logical options for that process. The examples described above therefore involve analytical data.

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GLOSSARY OF QUALITY ASSURANCE AND RELATED TERMS

Acceptance criteria — Specified limits placed on characteristics of an item, process, or service defined in requirements documents.

Accuracy — The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator. Examples of QC measures for accuracy include proficiency testing samples, matrix spikes, laboratory control samples (LCSs), and equipment blanks.

Action limit/level — The numerical value that causes a decision maker to choose or accept one of the alternative actions. It may be a regulatory threshold standard, such as a maximum contaminant level for drinking water; a risk-based concentration level; a technology limitation; or a reference-based standard.

Activity — An all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that, in total, result in a product or service.

Aliquot — A measured portion of a sample taken for analysis.

Analyte — A property which is to be measured.

Analytical batch — A group of samples, including quality control samples, which are processed together using the same method, the same lots of reagents, and at the same time or in continuous, sequential time periods. Samples in each batch should be of similar composition and share common internal quality control standards.

Assessment — As defined in the UFP-QAPP, the evaluation process used to measure the performance or effectiveness of a system and its elements against specific criteria.[1] Examples include, but are not limited to, audits, proficiency testing, management systems reviews, data quality assessments, peer reviews, inspections, or surveillance.

Audit (quality) — A systematic and independent examination to determine whether QA/QC and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives. *See also Technical Systems Audit.*

[1]This differs from the definition for *Assessments* in the UFP-QS due to the different scope of the two documents.

Bias — The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

Blank — A sample subjected to the usual analytical or measurement process to establish a zero baseline or background value; a sample that is intended to contain none of the analytes of interest. A blank is used to detect contamination during sample handling preparation and/or analysis.

Bottle blank — A sample designed to evaluate contamination introduced from the sample container(s) in a particular lot.

Calibration — A comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

Calibration standard — A substance or reference material used for calibration. *See also Calibration.*

Certification — The process of testing and evaluation against specifications designed to document, verify, and recognize the competence of a person, organization, or other entity to perform a function or service, usually for a specified time.

Chain of custody — An unbroken trail of accountability that ensures the physical security of samples, data, and records.

Characteristic — Any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable.

Coefficient of variation (CV) — A measure of precision (relative dispersion). It is equal to the standard deviation divided by the arithmetic mean. *See also Relative standard deviation.*

Co-located samples — See Field duplicates, co-located samples.

Comparability — The degree to which different methods or data agree or can be represented as similar. Comparability describes the confidence that two data sets can contribute to a common analysis and interpolation.

Completeness — A measure of the amount of valid data obtained from a measurement system compared with the amount that was expected to be obtained under correct, normal conditions.

Configuration — The functional, physical, and procedural characteristics of an item, experiment, or document.

Conformance — An affirmative indication or judgment that a product or service has met the requirements of the relevant specification, contract, or regulation; also, the state of meeting the requirements.

Contaminants of concern (COC) — The matrix-specific list of chemical compounds and analytes determined to be pertinent to a specific site or project; sometimes used interchangeably with target analytes.

Continuing calibration verification — A check of the initial calibration that is performed during the course of an analytical shift at periodic intervals using a Calibration Check Standard. Continuing calibration verification applies to both external standard and internal standard calibration techniques, as well as to linear and non-linear calibration models. The purpose is to assess the continued capability of the measurement system to generate accurate and precise data over a period of time.

Contractor — Any organization or individual contracting to furnish services or items or to perform work.

Corrective action — Any measures taken to rectify conditions adverse to quality and, where possible, to preclude their recurrence.

Data quality indicators (DQIs) — The quantitative statistics and qualitative descriptors that are used to interpret the degree of acceptability or utility of data to the user. The principal data quality indicators are precision, accuracy/bias, comparability, completeness, representativeness, and sensitivity.[2] Also referred to as data quality attributes.

Data quality objectives (DQOs) — Qualitative and quantitative statements derived from the data quality objectives (DQO) process, as defined by EPA QA/G-4. DQOs can be used as the basis for establishing the quality and quantity of data needed to support decisions.

Data quality objective (DQO) process — A systematic planning tool based on the scientific method that clarifies study objectives, defines the appropriate type, quantity and quality of data and specifies tolerable levels of potential decision errors needed to answer specific environmental questions and to support proper environmental decisions. The DQO process is one type of systematic planning process. *See also Systematic planning process.*

[2]The definition in the UFP-QS does not include sensitivity; however, sensitivity is considered a principal DQI in this Manual.

Data reduction — The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors, and collating them into a more useful form. Data reduction is irreversible and generally results in a reduced data set and an associated loss of detail.

Data review — The process of examining and/or evaluating data to varying levels of detail and specificity by a variety of personnel who have different responsibilities within the data management process. It includes verification, validation, and usability assessment.

Data user — Technical and other personnel responsible for engineering, scientific, and legal evaluations that are the basis for site decisions. Data users are responsible for determining data needs required to satisfy project objectives from their perspective (remedy, risk, compliance, etc.).

Decision-maker — Project manager, stakeholder, regulator, etc., who has specific interests in the outcome of site-related activities and will use the collected data to make decisions regarding the ultimate disposition of the site or whether to proceed to the next study phase.

Definitive data — Analytical data of known quality, concentration, and level of uncertainty. The levels of quality and uncertainty of the analytical data are consistent with the requirements for the decision to be made. Suitable for final decision-making. *See also Screening data.*

Design — The specifications, drawings, design criteria, and performance requirement; also, the result of deliberate planning, analysis, mathematical manipulations, and design processes.

Detection limit — A measure of the capability of an analytical method to distinguish samples that do not contain a specific analyte from samples that contain low concentrations of the analyte; the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated level of probability. Detection limits are analyte- and matrix-specific and may be laboratory-dependent. *See also Method detection limit, Quantitation limit, and Sample quantitation limit.*

Distribution — (1) The appointment of an environmental contaminant at a point over time, over an area, or within a volume; (2) a probability function (density function, mass function, or distribution function) used to describe a set of observations (statistical sample) or a population from which the observations are generated.

Document — Written text such as a report, standard operating procedure, plan. Once written, documents can be revised or amended, unlike records which are not revised once written.

Document control — The policies and procedures used by an organization to ensure that its documents and their revisions are proposed, reviewed, approved for release, inventoried, distributed, archived, stored, and retrieved in accordance with the organization's requirements.

Environmental conditions — The description of a physical matrix (e.g., air, water, soil, sediment) or a biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

Environmental data — Any parameters or pieces of information collected or produced from measurements, analyses, or models of environmental processes, conditions, and effects of pollutants on human health and the ecology, including results from laboratory analyses or from experimental systems representing such processes and conditions. It also includes information collected directly from measurements, produced from models, and compiled from other sources such as databases or the literature.

Environmental data operations — Any work performed to obtain, use, or report information pertaining to environmental processes and conditions.

Environmental monitoring — The process of measuring or collecting environmental data.

Environmental processes — Any manufactured or natural processes that produce discharges to, or that impact, the ambient environment.

Environmental programs — An all-inclusive term pertaining to any work or activities involving the environment, including but not limited to characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

Equipment blank — A sample of water free of measurable contaminants poured over or through decontaminated field sampling equipment that is considered ready to collect or process an additional sample. The purpose of this blank is to assess the adequacy of the decontamination process. Also called rinse blank or rinsate blank.

Estimate — A characteristic from the sample from which inferences on parameters can be made.

Field blank — A blank used to provide information about contaminants that may be introduced during sample collection, storage, and transport; also a clean sample exposed to sampling conditions, transported to the laboratory, and treated as an environmental sample.

Field duplicate (replicate) samples — 1) A generic term for two (or more) field samples taken at the same time in the same location. They are intended to represent the same population and are taken through all steps of the analytical procedure in an identical manner and provide precision information for the data collection activity. 2) The UFP-QAPP recognizes two categories of Field Duplicates Samples defined by the collection method, field duplicate, co-located samples and field duplicate, subsamples. *See also Field duplicate, co-located samples and Field duplicate, subsamples.*
Field duplicate, co-located samples — Two or more independent samples collected from side-by-side locations at the same point in time and space so as to be considered identical. These separate samples are said to represent the same population and are carried through all steps of the sampling and analytical procedures in an identical manner. These samples are used to assess precision of the total method, including sampling, analysis, and site heterogeneity. Examples of co-located samples include ambient air monitoring samples, surface water grab samples, and side-by-side sample core soil samples.

Field duplicate (replicate), subsamples — Duplicate (replicate) samples resulting from one sample collection at one sample location. For example, duplicate (replicate) subsamples may be taken from one soil boring or sediment core.

Finding — An assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive or negative and is normally accompanied by specific examples of the observed condition.

Graded approach — The objective process of establishing the project requirements and level of effort according to the intended use of the results and the degree of confidence needed in the quality of the results.

Guidance — A suggested practice that is not mandatory, intended as an aid or example in complying with a standard or requirement.

Guideline — A suggested practice that is not mandatory in programs intended to comply with a standard.

Hazardous waste — Any waste material that satisfies the definition of hazardous waste given in 40 CFR 261, “Identification and Listing of Hazardous Waste.”

Holding time — The period of time a sample may be stored prior to its required analysis.

Inspection — The examination or measurement of an item or activity to verify conformance to specific requirements.

Instrument blank — An aliquot of analyte-free water or solvent processed through the instrumental steps of the measurement process to determine the presence of carryover from the previous analysis. Analysis does not include any sample preparation.

Instrument performance check sample — A sample of known composition analyzed concurrently with environmental samples to verify the performance of one or more components of the analytical measurement process. Those components can include retention time, resolution, recovery, degradation, etc.

Interference — A positive or negative effect on a measurement caused by a analyte other than the one being investigated or other factors.

Internal standard — A standard added to a test portion of a sample in a known amount and carried through the entire determination procedure as a reference for calibrating and controlling the precision and bias of the applied analytical method.

Investigative organization — An entity contracted by the lead organization for one or more phases of a data collection operation.

Laboratory control sample — A sample of known composition prepared using contaminant-free water or in inert solid that is spiked with analytes of interest at the midpoint of the calibration curve or at the level of concern. It is analyzed using the same sample preparation, reagents, and analytical methods employed for regular samples.

Laboratory duplicates/replicates — Two or more representative portions taken from one homogeneous sample by the laboratory and analyzed in the same laboratory. Laboratory duplicate/replicate samples are quality control samples that are used to assess intralaboratory preparatory and analytical precision.

Laboratory fortified blank — A low-level laboratory control sample (e.g., at the quantitation limit) used to evaluate laboratory preparatory and analytical sensitivity and bias for specific compounds.

Lead organization — An entity responsible for all phases of the data collection operation.

Management — Those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management system — A structured, nontechnical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Matrix — The material of which the sample is composed, such as water, soil/sediment, or other environmental medium.

Matrix spike — A sample prepared by adding a known concentration of a target analyte to an aliquot of a specific homogenized environmental sample for which an independent estimate of the target analyte concentration is available. The matrix spike is accompanied by an independent analysis of the unspiked aliquot of the environmental sample. Spiked samples are used to determine the effect of the matrix on a method's recovery efficiency.

Matrix spike duplicate — A homogeneous sample used to determine the precision of the intralaboratory analytical process for specific analytes (organics only) in a sample matrix. The duplicate sample is prepared simultaneously as a split with the matrix spike sample, and each is spiked with identical, known concentrations of targeted analyte(s).

Mean (arithmetic) — The sum of all the values of a set of measurements divided by the number of values in the set; a measure of central tendency.

Measurement performance criteria — Acceptance limits selected for project-specific sampling and analytical systems that will be used to judge whether project quality objectives are met. *See also data quality indicators.*

Method — A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification), systematically presented in the order in which they are to be executed.

Method blank — A sample of a matrix similar to the batch of associated samples (when available) in which no target analytes or interferences are present at concentrations that impact the analytical results. It is processed and analyzed simultaneously with samples of similar matrix and under the same conditions as the samples.

Method detection limit — Minimum concentration of a substance that can be reported with 99 percent confidence that the analyte concentration is greater than zero. *See also Detection limit and Quantitation limit.*

Method detection limit studies — A statistical determination that defines the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the analyte concentration is greater than zero.

Must — When used in a sentence, a term denoting a requirement that has to be met.

Nonconformance — A deficiency in a characteristic, documentation, or a procedure that renders the quality of an item or activity unacceptable or indeterminate; nonfulfillment of a specified requirement.

Objective evidence — Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Observation — An assessment conclusion that identifies a condition (either positive or negative) that does not represent a significant effect on an item or activity. An observation may identify a condition that has not yet caused a degradation of quality.

Organization — A public or private company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, that has its own functions and administration.[3]

Outlier — A data point that is shown to have a low probability of belonging to a specified data population.

Parameter — A quantity, usually unknown, such as a mean or a standard deviation characterizing a population. *Parameter* is commonly misused for *variable*, *characteristic*, or *property*.

Precision — The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms. Examples of QC measures for precision include field duplicates, laboratory duplicates, analytical replicates, and internal standards.

Procedure — A specified way to perform an activity.

Process — A set of interrelated resources and activities that transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

Proficiency testing (PT) sample — A sample, the composition of which is unknown to the laboratory or analyst, which is provided to that laboratory or analyst to assess capability to produce results within acceptable criteria. PT samples can fall into three categories: (1) prequalification, conducted prior to a laboratory beginning project work, to establish initial proficiency; (2) periodic (e.g., quarterly, monthly, or episodic), to establish ongoing laboratory proficiency; and (3) batch-specific, which is conducted simultaneously with analysis of a sample batch. A PT sample is sometimes called a performance evaluation sample.

[3]When used in this Manual, the term is not limited to entities within a Federal Agency, as it is in the UFP-QS.

Proficiency testing sample, ampulated — A PT sample that is received as a concentrate and must be diluted to volume before being treated as an analytical sample. It can only be single blind.

Proficiency testing sample, full volume — A PT sample that is received by the laboratory ready to be treated as an analytical sample. It does not require dilution and therefore can be single or double blind.

Proficiency testing sample, site-specific — A PT sample created using a well-characterized contaminated matrix and treated as an analytical sample by the laboratory to test its capabilities.

Project — An organized set of activities within a program.

Project quality objectives (PQOs) — Qualitative and quantitative statements derived from a Systematic Planning Process (e.g., EPA QA/G-4 DQO process) that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors. PQOs will be used as the basis for establishing the quality and quantity of data needed to support decisions.

Project quantitation limit — The lowest concentration or amount of the target analyte required to be reported from a data collection project.

Quality — The totality of features and characteristics of a product or service that bears on its ability to meet the stated or implied needs and expectations of the user.

Quality assurance — An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

Quality assurance project plan (QAPP) — A formal document describing in comprehensive detail the necessary quality assurance (QA), quality control (QC), and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

Quality control — The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against “out of control” conditions and ensuring that the results are of acceptable quality.

Quality control sample — One of any number of samples, such as a PT sample, intended to demonstrate that a measurement system or activity is in control.

Quality management — That aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

Quality Management Plan — A formal document that describes the quality system in terms of the organization's structure, the functional responsibilities of management and staff, the lines of authority, and the required interfaces for those planning, implementing, and assessing all activities conducted.

Quality system — A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance (QA) and quality control (QC) activities.

Quantitation limit — The minimum concentration of an analyte or category of analytes in a specific matrix that can be identified and quantified above the method detection limit and within specified limits of precision and bias during routine analytical operating conditions.

Raw data — The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, hard copies of electronic data, magnetic tapes, untabulated sample results, QC sample results, printouts of chromatograms, instrument outputs, and handwritten notes.

Readiness review — A systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

Reagent blank — An aliquot of water or solvent free of measurable contaminants analyzed with the analytical batch and containing all the reagents in the same volume as used in the processing of the samples. The method blank goes through preparatory steps; the reagent blank does not.

Record (quality) — A document that furnishes objective evidence of the quality of products, services, or activities and that has been verified and authenticated as technically complete and correct. Records may include photographs, drawings, magnetic tape, and other data recording media.

Recovery — A measure of bias. Typically, a known concentration of analyte is spiked into an aliquot of sample. Both the spiked aliquot and an unspiked aliquot of sample are analyzed and the percent recovery is calculated.

Relative percent difference (RPD) — A unit-free measure of precision between duplicate analyses.

Relative standard deviation (RSD) — A unit-free measure of precision or variability. The RSD is also known as the Coefficient of Variation (CV) which is the standard deviation expressed as a percentage of the mean.

Remediation — The process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil matrices to a level that poses an acceptable risk to human health.

Replicate samples — Multiple duplicate samples.

Representativeness — A measure of the degree to which data accurately and precisely represent a characteristic of a population, a parameter variation at a sampling point, a process condition, or an environmental condition.

Reproducibility — The precision, usually expressed as variance, that measures the variability among the results of measurements of the same sample at different laboratories.

Requirement — A formal statement of a need and the expected manner in which it is to be met; documented statements that specify activities that must be done; the mandated activities.

Sample quantitation limit (SQL)– Quantitation limit adjusted for dilutions, for changes in sample volume or size, and extract and digestate volumes, percent solids, and cleanup procedures.

Scientific method — The principles and processes regarded as necessary for scientific investigation, including rules for formulation of a concept or hypothesis, conduct of experiments, and validation of hypotheses by analysis of observations.

Screening data — Analytical data of known quality, concentration, and level of uncertainty. The levels of quality and uncertainty of the analytical data are consistent with the requirements for the decision to be made. Screening data are of sufficient quality to support an intermediate or preliminary decision but must eventually be supported by definitive data before a project is complete.

Secondary Data — Data not originally collected for the purpose for which they are now being used. In addition, the level of QA/QC provided at the time of the original data collection may be unknown.

Self-assessment — The assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing or performing the work.

Sensitivity — The capability of a test method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. Examples of QC measures for determining sensitivity include laboratory-fortified blanks, a method detection limit study, and initial calibration low standards at the quantitation limit.

Service — The result generated by activities at the interface between the supplier and the customer; the supplier's internal activities to meet customer needs. Such activities in environmental programs include design, inspection, laboratory and/or field analysis, repair, and installation.

Shipping container temperature blank — A container of water designed to evaluate whether or not samples were adequately cooled during sample shipment.

Specification — A document stating requirements and referring to or including drawings or other relevant documents. Specifications should indicate the means and criteria for determining conformance.

Spike — A substance that is added to an environmental sample to increase the concentration of target analytes by known amounts. A spike is used to assess measurement accuracy (spike recovery). Spike duplicates are used to assess measurement precision.

Split sample — Two or more representative portions taken from a sample in the field or laboratory, analyzed by at least two different laboratories and/or methods. Prior to splitting, a sample is mixed (except volatiles, oil and grease, or when otherwise directed) to minimize sample heterogeneity. These are quality control samples used to assess precision, variability, and data comparability between different laboratories. (Split samples should be used when accompanied by a PT sample.)

Standard deviation — A measure of the dispersion or imprecision of a sample or population distribution; expressed as the positive square root of the variance, with the same unit of measurement as the mean.

Standard Operating Procedures (SOPs) — A written document that details the method for an operation, analysis, or action, with thoroughly prescribed techniques and steps. SOPs are officially approved as the methods for performing certain routine or repetitive tasks.

Storage blank — A sample composed of water free of measurable contaminants and stored with a sample set in the same kind of sample container. Storage begins upon receipt of sample shipment at the laboratory. The storage blank is analyzed at the end of the sample storage period to assess cross-contamination occurring during sample storage (typically analyzed only for volatile organic compounds).

Supplier — Any individual or organization furnishing items or services or performing work according to a procurement document or a financial assistance agreement. *Supplier* is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

Surrogate spike or analyte — A pure substance with properties that mimic the analyte of interest (organics only). Surrogates are brominated, fluorinated, or isotopically labeled compounds unlikely to be found in environmental samples. These analytes are added to samples to evaluate analytical efficiency by measuring recovery.

Systematic planning process — Systematic planning is a process that is based on the scientific method and includes concepts such as objectivity of approach and acceptability of results. Systematic planning is based on a common sense, graded approach to ensure that the level of detail in planning is commensurate with the importance and intended use of the work and the available resources. This framework promotes communication among all organizations and individuals involved in an environmental program. Through a systematic planning process, a team can develop acceptance or performance criteria for the quality of the data collected and for the quality of the decision.

Target analytes — The project-specific list of analytes for which laboratory analysis is required; sometimes used interchangeably with contaminants of concern.

Technical Systems Audit (TSA) — A thorough, systematic, on-site qualitative audit of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management, and reporting aspects of a system.

Traceability — The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.

Trip blank — A clean sample of water free of measurable contaminants that is taken to the sampling site and transported to the laboratory for analysis without having been exposed to sampling

procedures. Trip blanks are analyzed to assess whether contamination was introduced during sample shipment (typically analyzed for volatile organic compounds only).

Usability assessment — Evaluation of data based upon the results of data validation and verification for the decisions being made. In the usability step, reviewers assess whether the process execution and resulting data meet quality objectives based on criteria established in the QAPP.

Validation — Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. Data validation is a sampling and analytical process evaluation that includes evaluating compliance with methods, procedures, or contracts, and comparison with criteria based upon the quality objectives developed in the project QAPP. The purpose of data validation is to assess the performance associated with the sampling and analysis to determine the quality of specified data.

Variance (statistical) — A measure or dispersion of a sample or population distribution.

Verification — Confirmation by examination and provision of objective evidence that the specified requirements (sampling and analytical) have been completed. This is to be a completeness check.

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APPENDIX A

STANDARD OPERATING PROCEDURES

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APPENDIX A – STANDARD OPERATING PROCEDURES

As described in Section 3.0, Measurement and Data Acquisition Elements, all sampling and analysis procedures that will be used in the project must be documented in the QAPP or SOPs provided with or referenced in the QAPP. This appendix provides examples of SOP types, and some additional detail on their content.

A.1 Sampling Procedures

A.1.1 Sample Collection SOPs

Examples of sample collection SOPs include, but are not limited to, the following:

- Low Stress (low flow) Purging and Sampling Procedure for the Collection of Ground Water Samples from Monitoring Wells
- SOPs for Soil Sampling during Monitoring Well Installation
- Sampling SOPs for Surface and Subsurface Soils
- SOPs for the Collection of Sediments
- SOPs for the Collection of Surface Water Samples from Lakes, Ponds, and Streams
- SOPs for the Collection of Drinking Water from Residential Homes
- Sampling SOPs for Ambient Air, Stack Gases, and Soil Gas
- SOPs for Collection of Samples from Waste Storage Tanks and Waste Drums
- Sample Compositing SOPs
- Split Sampling SOPs

A.1.2 Equipment Cleaning and Decontamination SOPs

A.1.2.1 Equipment Cleaning SOPs

SOPs for equipment cleaning may be attached to or referenced in the QAPP. They should also be listed on the sampling SOP reference table (Figure 22 in Section 3.1.2). Initial equipment cleaning should address:

- How equipment will be cleaned prior to field activities
- Frequency at which equipment will undergo full cleaning protocols
- Criteria for measuring cleanliness

If precleaned bottles are used, the QAPP should identify the vendor and describe where the certificates of cleanliness will be maintained.

A.1.2.2 <u>Equipment Decontamination SOPs</u>

SOPs for equipment decontamination should be attached to or referenced in the QAPP. They should also be listed on the sampling SOP reference table (Figure 22). Decontamination procedures for each type of equipment should address:

- How equipment will be decontaminated in the field
- Frequency at which equipment will be decontaminated
- Criteria for measuring the effectiveness of the decontamination procedures
- Disposal of decontamination by-products, if applicable

A.1.3 Inspection and Acceptance SOPs for Supplies and Sample Containers

SOPs for inspection and acceptance of supplies and sample containers should include the following:

- Itemization of the supplies and sample containers that will be used when performing field activities, including sampling activities
- List of all supply and sample container vendors
- Description of the procedures that will be used to ensure that adequate supplies and sample containers are on hand and that sample containers are traceable and clean
- Procedures for tracking, storing, and recording supplies and lot numbers for sample containers
- Procedures for verifying container cleanliness, such as bottle blank analysis
- Frequency of inspection activities, acceptance criteria, and corrective action procedures employed to prevent the use of unacceptable supplies or sample containers
- List of personnel responsible for checking supplies, sample containers, and sample container certificates of cleanliness, by job function and organizational affiliation, and the personnel responsible for implementing corrective actions (If information is in an SOP, the SOP reference number should be cited and the SOP attached to the QAPP)

A.1.4 Field Documentation SOPs

The following information should be included in the field logbooks, field data collection forms, or electronic data instruments, if applicable:

- Site name and location
- Sample identification number
- Names, job functions, and organizational affiliations of personnel on-site
- Dates (month/day/year) and times (military) of all entries made in logbooks/forms
- User signatures
- Descriptions of all site activities, including site entry and exit times
- Site location by longitude and latitude, if known
- Weather conditions, including temperature and relative humidity
- Site observations
- Identification and description of sample morphology and collection locations

- Sample collection information, including dates (month/day/year) and times (military) of sample collections, sample collection methods and devices, station location numbers, sample collection depths/heights, sample preservation information, sample pH (if applicable), analysis requested (analytical groups), etc., as well as chain-of-custody information such as sample location identification numbers cross-referenced to field sample numbers
- Laboratories receiving samples and shipping information, such as carrier, shipment time, number of sample containers shipped, and analyses requested
- Contractor and subcontractor information (address, names of personnel, job functions, organizational affiliations, contract number, contract name, and work assignment number)
- Records of photographs taken
- Site sketches and diagrams made on-site

Because field information is matrix- and procedure-dependent, the information that will be recorded should be described for each matrix and each type of sampling procedure. For example, documentation of monitoring well sampling should include screen interval, pump intake, purge rate, purge volume, temperature, relative humidity, specific conductance, pH, redox potential, dissolved oxygen, and turbidity. For a soil boring, the documented field information should include drilling method, borehole diameter, ground elevation, and water level and soil descriptions should be in accordance with the Unified Soil Classification System or applicable ASTM procedures.

A.2 Analytical SOPs

Examples of analytical SOPs include, but are not limited to, the following:

- On-site Analytical SOPs
- Off-site Laboratory SOPs
- Sample Preparation SOPs
- Glassware Cleaning SOPs
- Calibration SOPs
- Maintenance, Testing, and Inspection Activities SOPs
- Analytical Standards Preparation and Traceability SOPs
- Data Reduction Procedures
- Documentation Policies/Procedures
- Data Review Procedures
- Data Management Procedures
- Sample and Sample Extract/Digestate Disposal SOPs

Calibration procedures may be documented separately in the QAPP or included in the appropriate analytical SOPs as attachments to the QAPP. In either case, the following items, where appropriate, must be addressed for each analytical procedure:

- Frequency of initial and continuing calibrations
- Number of calibration points, calibration levels for multipoint curves, and calibration standards at the required quantitation limit concentration for each target analyte/contaminant of concern

- Linearity calculation techniques
- Acceptance criteria for calibrations
- Calibration level for calibration verification standards (To assess instrument drift, a calibration verification standard should be run periodically during the analytical sequence and at the end of the analytical sequence.)
- Corrective actions for nonconformances
- Calibration and standards documentation, including a description of what documentation will be generated for calibrations and standards for each instrument (A plot for each regression curve should be provided for all nonlinear curves that will be used to quantitate field samples.)
- A description of the procedures to be used to ensure traceability of standards (Standards must be traceable to a verifiable source such as a NIST standard, if applicable.)
- A description of the use of second source verification standards

A.3 Sample Collection Documentation, Handling, Tracking, and Custody SOPs

Examples of sample collection documentation, handling, tracking, and custody SOPs include, but are not limited to, the following:

- Field Documentation SOPs and Records Management SOPs
- Sample Custody/Sample Security SOPs (field sampling)
- Sample Handling and Tracking SOPs (field sampling)
- Sample Packaging and Shipping SOPs (field sampling)
- Sample Receipt and Storage SOPs (laboratory analysis)
- Sample Custody/Sample Security SOPs (laboratory analysis)
- Sample Tracking SOPs (laboratory analysis)
- Sample Disposal or Archiving SOPs (laboratory analysis)

A.3.1 Sample Container Identification

Sample containers should be identified with the following minimum information:

- Site name and location
- Sample identification number
- Sample collection location and depth/height
- Collection date (month/day/year) and time (military)
- Sample collection method (composite or grab) and device
- Sample preservation method (chemical or physical, such as ice; indicate if sample must be light-protected)
- Sample pH, if applicable
- Analysis requested (analytical group)
- Sampler's signature

A.3.2 Sample Handling Procedures

Figure A-1 (QAPP Worksheet #26) provides an example of the Sample Handling System table that shows the flow of samples from the time of collection to laboratory delivery to final sample disposal.

SAMPLE COLLECTION, PACKAGING, AND SHIPMENT
Sample Collection (Personnel/Organization):
Sample Packaging (Personnel/Organization):
Coordination of Shipment (Personnel/Organization):
Type of Shipment/Carrier:
SAMPLE RECEIPT AND ANALYSIS
Sample Receipt (Personnel/Organization):
Sample Custody and Storage (Personnel/Organization):
Sample Preparation (Personnel/Organization):
Sample Determinative Analysis (Personnel/Organization):
SAMPLE ARCHIVING
Field Sample Storage (No. of days from sample collection):
Sample Extract/Digestate Storage (No. of days from extraction/digestion):
Biological Sample Storage (No. of days from sample collection):
Personnel/Organization:
Number of Days from Analysis:

Figure A-1. Sample Handling System (QAPP Worksheet #26)